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NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

[NRC–2008–0619]

RIN 3150–AI25

Requirements for Fingerprint-Based Criminal History Records Checks for Individuals Seeking Unescorted Access to Non-Power Reactors (Research or Test Reactors)

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to require non-power reactor (NPR) licensees to obtain fingerprint-based criminal history records checks before granting any individual unescorted access to their facilities. This action complies with the requirements of Section 652 of the Energy Policy Act of 2005 (EPAct), which amended Section 149 of the Atomic Energy Act of 1954, as amended (AEA), to require fingerprinting and a Federal Bureau of Investigation (FBI) identification and criminal history records checks of individuals permitted unescorted access to a utilization facility.

DATES: This rule is effective November 7, 2012.

ADDRESSES: You can access publicly available documents related to this rulemaking using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are online at the NRC's library at *http://www.nrc.gov/reading-rm/adams.html*. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov*.
- *Federal rulemaking Web site:* Public comments and supporting materials related to this final rule can be found at *http://www.regulations.gov* by searching on Docket ID: NRC–2008–0619. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Scott C. Sloan, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1619, email: *Scott.Sloan@nrc.gov*; or Ms. Beth Reed, Office of Nuclear Reactor Regulation, telephone: 301–415–2130, email: *Elizabeth.Reed@nrc.gov*.

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I. Background

Before the terrorist actions of September 11, 2001, the NRC regulations in Title 10 of the *Code of Federal Regulations* (10 CFR), Section 73.60, and 10 CFR 73.67 imposed physical protection requirements on NPRs [1] that included measures for storing and using special nuclear material (SNM) in controlled access areas, monitoring the controlled access areas for unauthorized activities, and ensuring a response to all unauthorized activities to protect SNM from theft or diversion. Subsequent to September 11, 2001, the NRC evaluated the adequacy of security at NPRs and considered whether additional actions should be taken to help ensure the trustworthiness and reliability of individuals with unescorted access to licensees' facilities. The NPRs were advised to consider taking immediate additional precautions, including observation of activities within their facility. Several NPRs have implemented additional security measures. The NRC evaluated these additional measures at each facility during the remainder of 2001.

From 2002 through 2004, the NPRs voluntarily implemented compensatory measures that included site-specific background investigations for individuals granted unescorted access to their facility. Depending on local restrictions, such as university rules, some of these background investigations included provisions for FBI fingerprint-based criminal history records checks, while checks at other NPRs include provisions for local or State law enforcement fingerprint-based criminal history records checks. Investigations at some NPRs did not include any fingerprinting. The NRC has also conducted security assessments at certain NPRs, which helped to identify risk-significant areas and materials.

Section 652 of the EPAct, enacted on August 8, 2005, amended Section 149 of the AEA to require fingerprinting and FBI identification and criminal history records checks for individuals ''permitted unescorted access to a utilization facility.'' The NPRs are included within the definition of what constitutes a utilization facility. Therefore, consistent with the requirement set forth in Section 149 of the AEA, any person granted unescorted access to an NPR must be fingerprinted

[1] All currently licensed research and test reactors (RTR) are non-power reactors. The NRC's regulations consider all RTRs a subset of non-power reactors (NPRs). The NPRs are defined in 10 CFR 50.2 and include utilization facilities licensed under Atomic Energy Act (AEA) Section 103 and 104. The use of the term NPR in place of RTR properly incorporates all Class 103 and Class 104 licensees defined in §§ 50.21 and 50.22 as utilization facilities, although there are currently no NPR licensees that are not RTRs. Therefore, the use of the term NPRs includes RTRs in this and all related rulemaking documents.

and have those fingerprints submitted to the Attorney General of the United States through the Commission for identification and a criminal history records check.

In SECY–05–0201, ''Implementation of the Energy Policy Act of 2005,'' dated October 31, 2005, the NRC staff informed the Commission of its plan for implementing the NRC's responsibilities under the EPAct. The Commission approved the staff's recommendations in a Staff Requirements Memorandum (SRM) dated January 5, 2006, and directed the staff to recommend appropriate interim regulatory actions that the NRC should implement while it developed the generic requirements for granting unescorted access, including the provisions in Section 652 of the EPAct pertaining to fingerprinting.

In SECY–07–0011, ''Interim Implementation of Fingerprinting Requirements in Section 652 of the Energy Policy Act of 2005,'' dated January 12, 2007, the NRC staff provided information and recommendations to the Commission on its EPAct interim implementation plan. In an SRM dated March 12, 2007, the Commission directed the NRC staff to expeditiously develop a definition of ''unescorted access'' that would apply to NPR licensees and issue orders to NPR licensees requiring fingerprinting for individuals that fall within this definition. In order to ensure compliance with Section 104c of the AEA, the NRC staff was directed to impose only the minimum amount of regulation needed for NPR licensees. The Commission also directed the NRC staff to proceed with a rulemaking to determine if additional personnel should be fingerprinted.

In response to the Commission's March 12, 2007, directive, the NRC imposed fingerprinting requirements for unescorted access to special nuclear material on the applicable NPR licensees by order (Order EA–07–074, ''Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Research and Test Reactors'' (72 FR 25337; May 4, 2007), and Order EA–07–098, ''Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to the General Atomics' Research and Test Reactors'' (72 FR 44590; August 8, 2007)). Specifically, the orders state that:

> An individual who is granted ''unescorted access'' could exercise physical control over the special nuclear material possessed by the licensee, which would be of significance to the common defense and security or would adversely affect the health and safety of the public, such that the special nuclear material could be used or removed in an unauthorized manner without detection, assessment, or response by systems or persons designated to detect, assess or respond to such unauthorized use or removal.

In implementing the requirement of the EPAct on an interim basis, the orders were issued requiring fingerprinting only for individuals with unescorted access to risk-significant materials (e.g., fuel), within the research and test reactor facilities. Licensees were required to submit fingerprints of individuals who were seeking or currently had unescorted access. Individuals who had previously been subjected to fingerprinting that would satisfy the requirements for unescorted access (e.g., access to safeguards information (SGI)) did not need to be fingerprinted again. These orders required that a reviewing official consider the information received from the FBI in conjunction with the other requirements for unescorted access to determine whether an individual may be granted or allowed continued unescorted access. The reviewing official was allowed to be the same official previously approved by the NRC for the SGI order (Order EA–06–203, ''Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Access to Safeguards Information,'' dated September 29, 2006; ADAMS Accession No. ML061510049) that implemented the EPAct fingerprinting and criminal history records check requirements for individuals who seek access to SGI.[2] The unescorted access order provided that an NRC-approved reviewing official was the only individual who could make the unescorted access determination.

Advance Notice of Proposed Rulemaking (ANPR) and Proposed Rule

On April 14, 2009 (74 FR 17115), the NRC published an ANPR to obtain stakeholder views on the issues associated with the proposal to require fingerprinting for criminal history records checks of individuals permitted unescorted access to NPRs. The ANPR indicated that the NRC was beginning the process of establishing generic requirements for NPR licensees to obtain fingerprints for criminal history records checks of individuals granted unescorted access to their facilities. The ANPR was intended to inform external stakeholders of the options the NRC was considering for implementing the fingerprinting requirements for NPR licensees as a proposed rule. The ANPR provided interested stakeholders an opportunity to comment on the options under consideration by the NRC. The NRC developed a proposed rule based on the feedback received on the ANPR and published the proposed rule on July 20, 2010 (75 FR 42000).

[2] The Safeguards Information orders were incorporated into 10 CFR part 73 on October 24, 2008 (73 FR 63546).

II. Public Comments on Proposed Rule

The public comment period for the proposed rule closed on October 4, 2010. In response to a stakeholder's request, the Commission directed the staff to reopen the public comment period. On December 20, 2010, the public comment period reopened (75 FR 79312) and subsequently closed on January 31, 2011. The NRC received six comment letters in response to its solicitation during the initial comment period and eleven comment letters during the reopened comment period. Many of the comments in these letters raised similar issues. A total of seventeen issues were identified, the majority of which were regarding differences from the 2007 NRC-issued orders, material criteria requirements, and area criteria requirements. The following is a summary of the public comments received and the NRC responses.

General Comments Received During Initial Public Comment Period

Comment: Several commenters expressed the view that existing NRC security orders as implemented and inspected at their facilities are workable and acceptable to codify. They stated that the wording of the proposed rule meets the principle of codifying the existing orders. However, these commenters further stated that the proposed wording goes beyond the scope of the existing orders without adequate justification. According to the commenters, ''The proposed rule does not adequately justify the expansion of requirements based on risk (risk informed) or performance issues (performance based) and, therefore, does not meet the staff's publicly stated basis for expanding regulatory requirements.''

The commenters further stated the expansion of the requirements in the proposed rule is counter to previously issued NRC documents assessing the risk and security of NPRs operated under the existing security orders and the cited Section 104c of the AEA provision on minimum regulation. ''By stated policy and statute the NRC seeks, wherever possible, to establish 'risk-informed regulation' and to 'impose only such minimum amount of

regulation.' This new regulation does not seem in keeping with those goals.''

Of particular concern to the commenters is the removal of ''public health and safety'' and ''common defense and security'' significance from the requirements for protection of SNM. They stated that the original orders implemented security enhancements (fingerprinting and background checks) to protect SNM of ''significance to the common defense and security'' or that would ''adversely affect the health and safety of the public.'' The comments reiterated a previous comment made in response to the NRC's ANPR (74 FR 17115; April 14, 2009), that the existing security orders as implemented and inspected at NPR facilities were adequate and acceptable. Any codification should reflect the existing orders and should not impose new requirements or definitions.

NRC Response: The NRC agrees that the wording of the proposed rule does not capture the wording of the NRC security orders verbatim. However, the NRC does not agree that failure to capture the wording of the orders verbatim constitutes an expansion of the orders' requirements. The NRC believes that the language of the final rule captures both the intent and the requirements of the security orders and does not constitute an expansion of the requirements with respect to SNM. The term, ''SNM,'' as used in the final rule language, maintains the same functional effect of the existing security orders' language and should be understood to be of such quantity and/or enrichment to be significant to the public health and safety and to the common defense and security.

Furthermore, the NRC does not agree that the requirements imposed by the final rule are inconsistent with previously issued NRC documents assessing the risk and security of NPRs or with Section 104c of the AEA. The NRC recognizes that the radiological risk posed by NPRs is relatively low and that this low risk informs the physical security requirements at NPRs. The NRC believes that the final rule presents a framework that minimizes the impact on NPR licensees, consistent with the ''minimal regulation'' requirement of the AEA by identifying specific, risk-significant areas within NPR facilities that satisfy the statutory requirement to fingerprint all persons seeking unescorted access to utilization facilities. The final rule fingerprints as few people as possible while still fulfilling the statutory requirement set forth in Section 149 of the AEA. No changes to the rule language were made as a result of this comment.

Comment: Several commenters stated that the original orders implemented security enhancements (fingerprinting and background checks) to prevent unauthorized use or removal of significant SNM ''without detection, assessment, or response by systems or persons.'' The proposed rule would remove this detection and response concept and require fingerprinting and background checks for individuals who are granted access to an ''area,'' regardless of whether such access would allow unauthorized use or removal without detection, assessment, or response. The removal of the ''detection, assessment, or response'' language is not consistent with the background discussion of the issue in the proposed rule (75 FR 42003), which states the rule would make use of this clause and flexibility.

NRC Response: The NRC agrees that the ''detection, assessment, or response'' language is not in the final rule. The purpose of this rulemaking is to establish requirements for fingerprinting those individuals seeking unescorted access to NPRs. The NRC believes that any individuals with unescorted access to SNM of such quantity and/or enrichment to be significant to the public health and safety and to the common defense and security or with unescorted access to vital areas at an NPR should be fingerprinted. The NRC believes this requirement to fingerprint for unescorted access to NPRs should be independent from the licensees' ability to ''detect, assess, or respond'' to an unauthorized removal of SNM. Furthermore, the NRC notes that there are existing detection, assessment, and response requirements set forth in §§ 73.60 and 73.67. Elimination of the ''detection, assess, and respond'' language in the final rule does not mean that licensees are no longer required to comply with existing detection, assessment, or response requirement. No changes to the rule language were made as a result of this comment.

Comment: Another commenter observed that the statements of consideration for the proposed rule states, ''* * * the provisions in this proposed rule are constructed to provide flexibility, providing both an 'area' criterion (unescorted access to vital areas) and a 'material' criterion (unescorted access to SNM).'' However, the proposed rule could be interpreted such that licensees would have to satisfy fingerprinting requirements for any personnel that would have access to vital areas or to materials. This could have the unintended result that licensees would have to meet both area and material criteria, which is at odds with the stated intention of providing flexibility. The commenter believes that the original 2007 NRC-issued security order wording should be used in § 73.57(g)(2)(ii).

NRC Response: The NRC agrees that the final rule will require licensees to comply with both vital area and SNM criteria when determining who needs to be fingerprinted when granted unescorted access to an NPR. The intent of the 2007 NRC-issued security orders was to enhance security at NPRs. The 2007 security orders limited fingerprinting for unescorted access at NPRs to a material criterion, with the understanding that the rulemaking process would evaluate additional fingerprinting requirements, including consideration of risk-significant areas. The NRC believes that inclusion of a vital area criterion in the final rule language is necessary to ensure adequate protection at NPRs.

However, the NRC believes that few NPRs will be affected by the vital area criterion because few NPR facilities have vital equipment besides SNM (unescorted access to which already requires fingerprinting due to the material criterion of this rule). Additionally, the NRC believes the impact of the vital area criterion will be minimal because those licensee personnel requiring unescorted access to vital areas will also likely require unescorted access to SNM or access to SGI (both of which already require fingerprinting).

The NRC believes that licensees will have flexibility in implementing the vital area criterion of this rule. Licensees are responsible for determining which equipment and areas within their facilities, if any, are vital, provided that licensees clearly document how they arrive at that determination, using the definitions of vital area and vital equipment in § 73.2. No changes to the rule language were made in response to this comment.

Comment: Several commenters were concerned with the addition of the term vital area. They stated that § 73.57(g)(2)(i) of the proposed rule, ''adds a new requirement to establish, define and control unescorted access to *vital areas* defined per Section 73.2. The need for this additional regulation was not adequately justified in the proposed rule basis when it stated the new rule uses definitions that already apply to all provisions within 10 CFR Part 73 and accordingly apply to RTR [NPR] licensees whose security requirements are governed by 10 CFR Part 73 * * *.''

The commenters assert that just because Section 149 of the AEA provides the Commission authority to

establish regulations (for fingerprinting and criminal history checks), that does not in itself justify the need for specific regulatory expansion. The recommendation is to remove the requirement for NPRs to evaluate for vital areas as currently defined in § 73.2 for power reactors. The commenters stated that current definitions for unescorted access placed by the NRC security order and defended by the staff as acceptable should be maintained or adequate justification through analysis should be provided supporting the need for additional regulation of vital areas.

NRC Response: The NRC agrees that the term ''vital area'' did not appear in the 2007 NRC-issued orders. However, the NRC disagrees that the inclusion of the vital area in the final rule language is a new requirement in itself. The term ''vital area'' is defined in § 73.2 as ''any area which contains vital equipment.'' ''Vital equipment,'' in turn, is defined in § 73.2 as ''any equipment, system, device, or material, the failure, destruction, or release of which could directly or indirectly endanger the public health and safety by exposure to radiation. Equipment or systems which would be required to protect public health and safety following such failure, destruction, or releases are also considered to be vital.''

The vital area concept is applicable to all utilization facilities, including NPRs. The NPRs that have a vital area are required to protect them in accordance with the requirements set forth in 10 CFR part 73. The only new requirement that the final rule imposes on NPR licensees that have a vital area is to fingerprint those individuals seeking unescorted access to these areas. This is consistent with the statutory requirement set forth in Section 149 of the AEA to fingerprint those individual granted unescorted access to a utilization facility.

The NRC disagrees with the comment that the amended Section 149 of the AEA does not in itself justify the need for specific regulatory expansion. However, the NRC believes that the impact of the vital area criterion will be minimal because few NPR facilities have vital equipment besides SNM (unescorted access to which already requires fingerprinting due to the material criterion of this rule). Additionally, the NRC believes the impact of the vital area criterion will be minimal because few licensee personnel will require unescorted access to vital areas that do not require unescorted access to SNM or to SGI. In the development of this rulemaking, the NRC re-evaluated whether an area criterion, as applied to the requirements of fingerprinting individuals seeking unescorted access to the facility, is required to ensure that the fingerprinting requirements in Section 149 of the AEA are properly and completely implemented for NPRs. The rule bifurcates the fingerprint requirement for ''access to a utilization facility'' into two criteria, which the rule terms ''SNM'' and ''vital area''—both of which licensees must comply with by the implementation date of this rule. The NRC made an affirmative determination that both a material criterion and an area criterion are required to implement the statutory requirements of Section 149 of the AEA for NPR facilities.

Comment: One commenter stated, ''* * * the [statements of consideration] for the section [73.57(g)(2)(i)] indicates a significant burden for licensees when it states, '* * * implementation of this proposed revision may involve a significant amount of interpretation on the part of [NPR] licensees, the NRC expects that [NPR] licensees would have clear documentation to support their decisions. (75 FR 42008)' ''

NRC Response: The NRC disagrees with the comment that a significant burden will be placed on licensees. The NRC believes that the final rule language is clear and will not require significant interpretation beyond that provided in the statements of consideration. The purpose of including well-defined area and material criteria is to lessen the need for licensees to interpret when fingerprinting is required. Furthermore, the NRC does not believe that requiring licensees to document their access authorization determinations poses an undue burden.

Comment: Another commenter referenced the NRC's assertion in the proposed rule, which stated, ''The equipment, systems, devices, and material that fall within Section 73.2 vital equipment definition meet the utilization facility definition in Section 11.cc of the AEA. Hence, fingerprinting individuals who wish to have unescorted access to vital areas is ensuring that individuals permitted access to the 'utilization facility,' as defined in the AEA, is properly implemented in the NRC's regulations.'' The commenter expressed the view that this statement implies every piece of equipment and all materials within a ''utilization facility'' (i.e. a 10 CFR Part 50 licensed nuclear reactor facility) are considered vital rather than specific areas or equipment. The commenter stated that this statement is ''grossly incorrect;'' therefore, any subsequent conclusions that this statement intended to support should be considered questionable. The § 73.2 definition of vital equipment applied at the National Institute of Standards and Technology Center of Neutron Research bounds the limiting Maximum Hypothetical Accident (MHA) to protect the health and safety of the general public and the protection of SNM in quantities significant to the common defense and security. Vital equipment or areas have been defined and explained in the NRC-approved Physical Security Plan and reviewed for adequacy and correctness within NRC-sponsored Physical Security Assessments for the National Bureau of Standards Reactor. The definition of vital area and vital equipment as applied has been reviewed under the current threat environment by the NRC so there should be no requirement or expectation for NPR licensees to provide additional ''clear documentation to support their decisions'' under the proposed rule.

NRC Response: The NRC agrees that not every piece of equipment within an NPR meets the definition of vital equipment contained within a vital area. As noted above, the terms ''vital equipment'' and ''vital area'' have specific definitions within 10 CFR part 73. The NRC established the vital area and SNM criteria for this rule as a means to define the specific areas for which individuals must be fingerprinted when seeking unescorted access to an NPR. Many NPR facilities are located within classroom or laboratory buildings with no clear demarcation between the reactor facility and unrelated areas. Therefore, many persons pass through the buildings housing NPR facilities who are not affiliated with the reactor itself. Instead of requiring fingerprinting for every person entering the building that houses the reactor facility, the NRC believes that the use of the vital area and SNM criteria to determine which personnel must get fingerprinted fulfills the statutory requirement of Section 149 of the AEA. No changes to the rule language were made as a result of this comment.

Comment: Another commenter expressed the view that the phrasing of the proposed language in § 73.57(g)(1) that states: ''No person shall be permitted unescorted access to a non-power reactor facility unless that person has been determined by an NRC-approved reviewing official to be trustworthy and reliable based on * * *'' could result in the misinterpretation that fingerprinting requirements must be met for access to any part of a non-power reactor facility, which is not the stated intention of the proposed rule. Such a misinterpretation

might be avoided by stating that: ''No person shall be permitted unescorted access at a non-power reactor facility unless that person has been determined by an NRC-approved reviewing official to be trustworthy and reliable based on * * *''

NRC Response: The NRC disagrees with this comment. Paragraph g(2) of the rule identifies specific areas within the NPR facility, unescorted access to which requires an FBI fingerprint-based criminal history records check. The NRC believes that the inclusion of area and material criteria makes it clear when licensees must fingerprint individuals seeking unescorted access to the NPR. No changes to the rule language were made as a result of this comment.

Comment: One commenter recommended that in addition to specifying the requirements in accordance with NRC order EA–07–074, the rule could state: ''* * * licensees *may* specify vital areas for which fingerprinting requirements must be met to ensure that those without unescorted access could not exercise physical control over materials.''

NRC Response: The NRC disagrees with this comment. The NRC believes requiring fingerprint-based criminal history records checks for those seeking unescorted access to vital areas, as defined in § 73.2, is critical in fulfilling the statutory requirements of Section 149 of the AEA. Use of the phrase recommended by the commenter does not convey the appropriate obligation of licensees to implement the requirements of the final rule. No changes to the rule language were made as a result of this comment.

Comment: Several commenters expressed the view that § 73.57(b)(2)(i) appears subordinate and redundant to § 73.61. They believe that § 73.61 should be updated and referenced as opposed to adding new exceptions in § 73.57.

NRC Response: The NRC disagrees with the comment. The Commission previously addressed this topic on February 2, 2007 (72 FR 4948), in the § 73.61 rulemaking, ''Relief from Fingerprinting and Criminal History Records Checks.'' Although similar, § 73.61 provides relief from fingerprinting requirements for certain categories of individuals considered trustworthy and reliable to permit unescorted access to radioactive material or other property. Paragraph (b)(2)(i) of § 73.57 offers similar relief for unescorted access to utilization facilities or SGI. This rule is specific to non-power reactors and is best contained in a single section of 10 CFR part 73 (i.e., § 73.57). No changes to the rule language were made as a result of this comment.

Comment: Several commenters stated that in public meetings, stakeholders have requested relief from the requirement that the only basis for unescorted access is fingerprints submitted through the NRC to the Attorney General; instead of allowing for other mechanisms to achieve the same end of providing criminal history records check from the FBI. The NRC has previously stated that this is required by Section 149 of the AEA. While Section 149a does mandate this mechanism, Section 149b states: ''The Commission, by rule, may relieve persons from the obligations imposed by this section, under specified terms, conditions, and periods, if the Commission finds that such action is consistent with its obligations to promote the common defense and security and to protect the health and safety of the public.'' The NRC has made use of this exception in the proposed § 73.57(b)(2)(i) and in existing § 73.61. Therefore, the mechanism for relief is within the statute, with the basis that the action (fingerprint and criminal history records checks by other mechanisms) is equivalent to Section 149a and therefore ''consistent with its (the NRC's) obligations to promote the common defense and security and to protect the health and safety of the public.''

NRC Response: The NRC disagrees with the comment suggestion to the extent that it is asking for alternative methods to those that are set forth in Section 149 of the AEA. The NRC notes that Section 149 requires the Commission to fingerprint any person granted unescorted access to a utilization facility. Section 149.a.(2) of the AEA requires that these fingerprints be submitted to the Attorney General of the United States through the Commission for identification and a criminal history records check. The Commission does not have discretion to deviate from this statutory requirement.

The commenter correctly notes that Section 149.b of the AEA allows the Commission, by rule, to relieve persons from the obligations imposed by Section 149.a of the AEA. The exemptions listed in § 73.57(b)(2)(i) and in existing § 73.61 include persons who are considered trustworthy and reliable by virtue of their occupational status and have either already undergone a background or criminal history records checks as a condition of their employment, or are subject to direct oversight by government authorities in their day-to-day job functions. No changes to the rule language were made as a result of this comment.

Comment: Several commenters expressed the view that the NRC has the authority to waive the fees it charges to process fingerprints and criminal history records checks. They disagreed with a previous NRC response that Section 149 of the AEA ''explicitly requires'' fees be collected and ''the NRC does not have authority to waive the fee'' (75 FR 42003). The commenters assert that Section 149.e of the AEA states, ''The Commission *may* establish and collect fees to process fingerprints and criminal history records under this section,'' but it does not require it. The commenters conclude by stating, ''The AEA Chapter 4 also directs the Commission 'to exercise its powers in a manner to * * * insure the continued conduct of * * * activities at support research facilities * * *' Therefore, waiver of any additional NRC administrative cost in 10 CFR 57(d)(3)(ii) for NPR institutions will promote both the implementation of the proposed rule and the intent of AEA Chapter 4.''

NRC Response: The NRC is sensitive to the costs involved in regulation. The fees charged to NPR facilities for fingerprinting are the direct costs incurred from the U.S. Department of Justice for fingerprint processing. No changes to the rule language were made as a result of this comment.

Comment: Several commenters stated that the readability of 10 CFR part 73 is problematic and gave various suggestions. They stated that 10 CFR part 73 is a complicated part with many facets that dictate stringent requirements on nuclear power plants. Portions of the regulation are applicable to NPRs. It is a difficult part to navigate and determine applicability. Adding more sections to this rule, using the definitions section of the part and using legalistic language does not meet the intent of Presidential Direction on ''Plain Language in Government Writing'' or assist the Commission in meeting the AEA direction on minimal regulation of NPRs. Some improvements that could easily be incorporated include: (1) A clear applicability statement (§ 73.57(a)(1)) (this section currently says (in essence) that § 73.57 is applicable to all licensees engaged in any activity subject to Commission regulation; this does not seem correct and does not promote ease of use of the regulation); (2) clear applicability for each paragraph section; (3) shorter sentences and/or bulleted lists to simplify paragraphs; and (4) less use of references to other sections and/or short description of the section (example

§ 73.2 (Definitions) or § 73.61 (Relief from Fingerprinting)).

NRC Response: The NRC agrees with the comment that 10 CFR part 73 is complicated, and acknowledges that those unfamiliar with the regulations may have some difficulty understanding them. The NRC is willing to provide outreach and education to assist licensees in understanding the final rule. The NRC decided to use § 73.57 for processing fingerprints so that NPR licensees and future non-power reactor licensees will have their fingerprints taken, handled, and processed in a manner consistent with other fingerprinting requirements including the NPR fingerprinting orders and the SGI fingerprinting regulations.

From a regulatory standpoint, putting another set of fingerprinting requirements somewhere else in the regulations would be redundant and would further complicate the readability of 10 CFR part 73. No changes to the rule language were made as a result of this comment.

Comment: One commenter supported the rulemaking as written, but expressed that any further regulations in regard to any additional background investigation requirements above and beyond fingerprinting should be left to the individual NPR licensees. The commenter felt that the NPR licensee is in the best position to decide what additional, if any, information is necessary to determine the trustworthiness and reliability of an individual seeking unescorted access and that this is consistent with the NRC's obligation under Section 104c of the AEA to put in place the minimum requirements for NPR licensees.

NRC Response: The NRC agrees with this comment. Licensees are responsible for determining the trustworthiness and reliability of persons granted unescorted access to their facilities in accordance with the requirements set forth in the NRC regulations. The NRC does not anticipate adding any additional requirements beyond the fingerprinting requirement to NPR licensees at this time. Licensees may decide to review additional information beyond that required by NRC regulations, consistent with applicable Federal and State laws, if the licensee determines that such information is necessary to make an adequate trustworthiness and reliability determination. No changes to the rule language were made as a result of this comment.

Comment: One commenter stated that the NPR facilities did not have a clear understanding of the consequences of the rule and requested that the NRC extend the comment period to coincide with the expiration of the proposed rule for 10 CFR part 37 on January 31, 2011.

NRC Response: The NRC understands the comment and reopened the public comment period on December 20, 2010 (75 FR 79312). The extended comment period remained open until January 31, 2011.

Comment: Several commenters expressed the view that employees who are not NRC employees but are employed by State or Federal Governments are subject to fingerprint/background checks as a condition of employment and for obtaining security clearances. Equivalence needs to be established to reduce the burden and expense associated with clearing the same individual multiple times.

NRC Response: The NRC agrees with this comment. The final rule language is modified to include State and Federal non-NRC employees to those exempt from additional fingerprinting in § 73.57(b)(2)(i).

Comment: One commenter stated that the use of fingerprints to perform domestic criminal history records checks does not provide sufficient background information on foreign individuals seeking unescorted access and gives the illusion of a thorough check, when only a fraction of the individual's criminal history may be covered by U.S. records. The commenter recommended the criminal history records check include a foreign individuals' home country or international police cooperation to perform a criminal history records check in their previous nation of residence, and to include a check against the terrorist watch list.

NRC Response: The NRC agrees that FBI fingerprint checks are likely only to give information about domestic criminal history. Fingerprinting has long been a trusted method of verifying an applicant's identity, and it serves as an accepted method of searching existing U.S. records for domestic criminal history. The scope of this proposed rulemaking is to develop regulations implementing the fingerprint requirements set forth in Section 149 of the AEA. Section 149.a.(2) of the AEA requires that, ''All fingerprints obtained by an individual or entity * * * be submitted to the Attorney General of the United States through the Commission for identification and a criminal history records check,'' for those seeking or permitted unescorted access to utilization facilities. The NRC recognizes that an FBI criminal history records check may be only one aspect of a licensee's determination to grant an individual unescorted access to an NPR. Many licensees undertake more extensive background investigations as they deem necessary. No changes to the rule language were made as a result of this comment.

General Comments Received During Reopened Public Comment Period

All eleven comments received during the reopened public comment period referred to the proposed rule and previously submitted public comments provided by other facilities and the National Organization of Test, Research, and Training Reactors (TRTR). All eleven comments supported TRTR's comments submitted on October 3, 2010 (NRC–2008–0619–0019), which are addressed previously in this document under, ''General Comments Received During Initial Public Comment Period.'' The sentiments stated that the proposed rule adds additional requirements for security at NPR facilities that will further limit student, faculty, and research access and divert additional resources from educational and research missions. Some of the eleven comments provided views that were in addition to those supporting TRTR's comments. The following are those additional comments received during the reopened public comment period.

Comment: Several commenters expressed the view that there is no clear evidence these additional requirements will provide a commensurate improvement in the protection of public health and safety. They stated that after the events of September 11, 2001, the NRC required compensatory measures that were implemented by all NPR facilities via the Confirmatory Action Letter process. Several years later, the NRC issued order EA–07–074, requiring fingerprinting and criminal history records checks for individuals with unescorted access as defined by the order. In the decade since September 11, 2001, there have been no credible threats to security at NPRs. The measures and order implemented since then have provided more than adequate additional protections given the implications of that historic occurrence. With no indications of an increased probability of threat against NPRs, there can be no justification for further prescribed additional security requirements which heretofore have been adequate.

NRC Response: The NRC agrees that there is no current, specific, credible threat to the security of NPRs. Furthermore, the NRC agrees that NPR security requirements, including regulations, NRC-issued security orders, and compensatory measures have provided adequate protection at NPRs to

date. However, the NRC is required under Section 149 of the AEA to implement the requirement to fingerprint all persons seeking unescorted access to utilization facilities, including NPRs. Since 2007, the NRC has relied on security orders to fulfill this statutory requirement, but the NRC prefers to regulate by rulemaking vice regulating by orders. The rulemaking process allows deliberate processes and extensive stakeholder involvement that orders do not. The 2007 NRC-issued security orders have provided adequate protection and allowed a shorter implementation time, but this final rule has been shaped by lessons learned from the orders, rulemaking process best practices, and engagement from the NPR community.

Comment: Two commenters stated similarly that they believed the proposed rule would begin limiting the educational opportunities at many facilities without further advancing the security of these facilities. The proposed rule adds additional requirements for security at NPR facilities that will very likely limit student, faculty, and researcher access and divert additional resources from their educational and research missions. They note that in difficult budget times, resources are very tight and funding support at the State level is already limited. Additional requirements would likely further reduce the educational and research capabilities of some facilities to the point where they may be closed and cease to contribute to these missions and the nuclear education in our country. They have no problem with the need to provide a secure and safe environment, but feel that current procedures are more than adequate so that the proposed additional requirements add extremely little to that environment (if anything) while diverting both attention and resources from more important matters.

NRC Response: The NRC is sensitive to the costs of regulation. The only requirement in this final rule that is additional to the 2007 NRC-issued security orders is to fingerprint those persons seeking unescorted access to vital areas. As stated above, the NRC believes the impact of the vital area criterion will be minimal because few NPR facilities have vital equipment besides SNM (unescorted access to which already requires fingerprinting due to the material criterion of this rule). Additionally, the NRC believes the impact of the vital area criterion will be minimal because few licensee personnel will require unescorted access to vital areas that do not require unescorted access to SNM or to SGI. In the development of this rulemaking, the NRC re-evaluated whether an area criterion, as applied to the requirements of fingerprinting individuals seeking unescorted access to the facility, is required to ensure that the fingerprinting requirements in Section 149 of the AEA—the regulatory basis by which this rulemaking was initiated—are properly and completely implemented for NPRs. The rule bifurcates the fingerprint requirement for ''access to a utilization facility'' into two criteria which the rule terms ''SNM'' and ''vital area''—both of which licensees must comply with by the implementation date of this rule. The NRC made an affirmative determination that both a material criterion and an area criterion are required to implement the statutory requirements in Section 149 of the AEA for NPR facilities.

Comment: Another commenter was concerned that the proposed rule would further discourage utilization of research reactor facilities by individuals who pose essentially no security risk. The commenter stated that many reactors today already face the prospect of diminished utilization and anything that would further discourage potential users will have a detrimental impact on the viability of these facilities. The commenter concluded that any regulations proposed by the NRC should have an adequately demonstrated basis in terms of information available in the public record. The commenter was unaware of any serious security incidents, such as attempted theft of SNM or sabotage of reactor facilities, by persons without fingerprinting checks. The commenter recommended that cognizant Federal agencies should use caution in broadly applying new rules, particularly without taking into account the added paperwork burdens and costs associated with such rulemaking. This impact can be particularly devastating for smaller research reactor facilities that are already under considerable budgetary pressure from their host institutions.

NRC Response: The NRC does not intend to discourage utilization of research reactor facilities in any way. However, the principle focus of this rule is to implement Section 149 of the AEA as amended, which requires fingerprinting of all individuals given unescorted access to an NPR. The NRC believes that this requirement presents a minimal burden to NPRs as the differences between this final rule and the 2007 NRC-issued security orders are minimal. In order to ensure complete and proper implementation of the statute's requirements for both current NPR licensees and future NPRs, this rulemaking incorporates an additional area criterion beyond the SNM criterion invoked by the order. The area criterion is to ensure that individuals seeking unescorted access to areas that contain vital equipment are fingerprinted and thereby receive FBI fingerprint-based criminal history records checks.

Comments Responding to NRC-Posed Questions

In the proposed rule **Federal Register** notice dated July 20, 2010 (75 FR 42008), the NRC requested stakeholder feedback on additional topics. The three questions presented were:

1. Is 120 days sufficient time to implement the new provisions, including revising or developing fingerprinting programs or procedures?
2. Are there any other newly issued NRC requirements or impositions (aggregate impacts) that you expect could adversely impact your ability to implement the proposed provisions?
3. If there are other potential aggregate impacts, is there a time when you expect that these impacts will become insignificant in terms of your capability to implement the new proposed revisions?

Comment: The NRC received 3 total responses to the question concerning the implementation of § 73.57. Two commenters stated that the 120 days for implementation is sufficient time provided that individual licensees may request an extension based on other activities and limited staff resources. One of the commenters stated that this time period was sufficient only if the rule was amended as they had requested.

NRC Response: The NRC understands the concern regarding the implementation period. Accordingly, the NRC held a Category 3 public meeting on June 23, 2011, to better understand concerns associated with implementation. The effective date of the rule was extended to 180 days in response to these concerns to enable implementation planning meetings with all affected stakeholders. Given the NRC security orders already in place, the NRC will allow 180 days for full implementation of this rule to provide for a smooth transition in adoption of this regulation.

Comment: In response to the NRC question whether there are other newly issued NRC regulations that have an aggregate impact to implementing § 73.57, several commenters stated that the proposed rule for 10 CFR Part 37, ''Physical Protection of Byproduct Material'' (75 FR 33902; June 15, 2010), will impact their ability to implement § 73.57 as the same process and

procedures are impacted by both rules. The actual impact of 10 CFR Part 37 (as with the final § 73.57) is unknown as the rule is in draft.

One commenter continued by stating that they identified no specific aggregate impact, but if the proposed rule were implemented as worded, multiple areas will be declared vital areas, facility access will be further restricted, SNM of no significance will be removed from temporary storage areas and moved into the vital controlled access areas, research/education activities using these materials will be halted if necessary to comply with the regulation until suitable protections can be evaluated, and clear documentation established. This commenter requested that NRC ensures regulatory discretion remains for individual licensees when implementing the new rule.

Another commenter continued by stating that individual licensees may have aggregate impacts (such as ongoing licensing actions or relicensing) and also recommended that the NRC ensure regulatory discretion remains when implementing the new rule.

NRC Response: The NRC disagrees with the comments with regard to the implementation challenges. As noted in response to the previous comments, the NRC extended the effective date of the rule to 180 days and NRC staff will meet with NPR licensees to support implementation. Regarding the relationship of proposed 10 CFR part 37, ''Physical Protection of Byproduct Material'' (75 FR 33902; June 15, 2010), and this rulemaking, 10 CFR part 37 would deal specifically with the use and transport of Category 1 and Category 2 quantities of radioactive material as defined in proposed 10 CFR part 37. The changes to § 73.57 presented in this final rule are written specifically to ensure proper fingerprinting for unescorted access to SNM and vital areas at NPRs. As such, this amendment to § 73.57 is separate and distinct from the provisions that the NRC may incorporate into 10 CFR part 37 to address radioactive material.

The use of the vital area criterion expands a requirement to fingerprint individuals who wish to have unescorted access to areas in NPRs that may not contain SNM, but instead may contain *vital equipment* that is important from a radiological sabotage standpoint (i.e., if it is a vital area that is established to contain only SNM, then that is already captured in the SNM criterion). The term *vital area* is used in its definition found in § 73.2. As such, only those NPR licensees who have *vital areas* as defined in 10 CFR part 73 are likely subject to this added requirement. This vital *equipment* would likely exist only at the higher power NPRs, and the vital areas where they are contained can be identified by reference to the current security plans and informed by the security assessments. For most NPR facilities, the SNM criterion adequately ensures that individuals who wish to have unescorted access are fingerprinted. No regulatory discretion is allowed for this rule; however, the NRC staff will work with NPR licensees to support proper interpretation and implementation of these criteria.

III. Discussion

A. General

These amendments establish generically applicable fingerprinting requirements for non-power reactor licensees similar to those previously imposed by the Commission's orders pertaining to the granting of unescorted access. The amendments implement the requirement in Section 149.a.(1)(B)(i)(I) of the AEA that the Commission require to be fingerprinted any individual who is permitted unescorted access to a utilization facility.

As previously noted, Section 149 of the AEA requires that the Commission fingerprint and conduct a criminal history records check of individuals seeking unescorted access at a broader range of NRC licensees and regulated facilities. Utilization facilities, including NPRs, which were not previously subject to these requirements, are now subject to these fingerprint requirements. It is this specific expansion in regulatory authority that is the subject of this proposed rule (i.e., extension of these fingerprint-based FBI criminal history records check requirements to NPRs).

Section 149 of the AEA now requires fingerprinting for individuals seeking unescorted access to a ''utilization facility.'' ''Utilization facility'' is a term that is defined in Section 11.cc. of the AEA as: ''any equipment or device, except an atomic weapon, determined by rule of the Commission to be capable of making use of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public, or peculiarly adapted for making use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public; or any important component part especially designed for such equipment or device as determined by the Commission.''

The Commission has defined ''utilization facility'' in § 50.2 as any nuclear reactor other than one designed or used primarily for the formation of plutonium or uranium-233.

In developing these provisions, the NRC recognized that when constructing requirements for NPR licensees, it should be cognizant of the direction in Section 104.c of the AEA which states, in part, that the Commission is directed to impose only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations under the Act to promote common defense and security and to protect the health and safety of the public and will permit the conduct of widespread and diverse research and development.

The revisions discussed in this document are constructed in accordance with the requirements of Section 149 of the AEA and within the constraints of Section 104.c of the AEA.

B. Relaxing of Orders

Section 73.57 as amended replaces, in whole, the interim requirements imposed by Order EA–07–074, ''Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Research and Test Reactors'' (72 FR 25337; May 4, 2007); and Order EA–07–098, ''Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to the General Atomics' Research and Test Reactors'' (72 FR 44590; August 8, 2007). The final rule amends § 73.57 with similar requirements that ensure proper implementation of the requirements in Section 149 of the AEA. Accordingly, once current NPR licensees have implemented the requirements in § 73.57, the NRC will relax Order EA–07–074 and Order EA–07–098 after compliance with the requirements of the final rule has been documented. However, all orders will remain in effect until the NRC notifies the current NPR licensee, in writing, that the orders are relaxed with respect to its facility.

C. Implementation Plans

The effective date of this rule is November 7, 2012 which will allow 180 days for implementation. This is 60 days more than the 120 originally proposed time period in response to public comments. The NRC believes that the majority of procedure and plan changes are currently in place as a result of the previously issued unescorted access order. But, some licensees stated that they would need additional time.

The extended effective date of this final rule will provide time for those licensees to develop or revise procedures and programs associated with the granting of unescorted access at their facilities to comply with the final § 73.57(g) provisions. There are no safety or security issues associated with this additional time because the security orders have already been in place for a number of years. Additionally, the NRC believes this provides sufficient time for additional individuals to be fingerprinted and approved by the reviewing official.

The NRC held a Category 3 public meeting on June 23, 2011 (ADAMS Accession Nos. ML111460100 and ML111821113). The principal objective of this Category 3 public meeting was to continue outreach in support of openness and transparency and to facilitate communication that would enhance better understanding, interpretation, and implementation of this regulation. The NRC staff intends to offer an informed series of site-specific implementation meetings for each licensee. The intent of these meetings is to facilitate communication and provide the licensees an opportunity to discuss how they will ensure compliance with this rule.

IV. Paragraph-by-Paragraph Analysis

A. § 73.57(a) General

Paragraphs (a)(1) and (a)(2) are simplified because the first portion of the current regulations, which includes current power reactors licensed under 10 CFR Part 50 and applicants for power reactor licenses, is encompassed by the second portion of the provision that requires licensees that engage, or intend to engage in any regulated activity, be subject to the provisions of § 73.57.

Paragraph (a)(3) is revised to add NPRs into the scope of licensees subject to § 73.57 fingerprint provisions. Non-power reactor licensees will be added to § 73.57 to make use of the current fingerprint requirement provisions that are being successfully used for other licensees subject to FBI fingerprint-based criminal history records checks. This will ensure that NPR licensee fingerprints are handled in a manner that is both consistent with the process used for other licensees, and that ensures the NRC meets it obligations under the AEA for the handling and processing of fingerprints with the FBI.

B. § 73.57(b) General Performance Objective and Requirements

Paragraph (b)(1) is revised to include non-power reactor licensees in the scope of the general performance and objective requirements of § 73.57. The paragraph points to new paragraph (g) where the specific unescorted access provisions for NPR licensees are described.

Paragraph (b)(2)(i) is revised to add non-power reactor facilities. Paragraph (b)(2)(i) is further revised to list ''offsite response organizations responding to a non-power reactor facility'' as one of the categories that does not require fingerprinting under the revised § 73.57 provisions. Based on comments received in response to the proposed rule, paragraph (b)(2)(i) is further revised to add ''Federal'' (non-NRC) employees who have had equivalent reviews of FBI criminal history data to the list of individuals that licensees need not fingerprint in accordance with the requirements of this section.

Paragraph (b)(2)(v) is added to enable individuals who have a valid unescorted access authorization to a non-power reactor facility on the effective date of the rule (granted in response to NRC Orders EA–07–074 and EA–07–098) to retain their access authorization and not be required to have a new fingerprint-based FBI criminal history records check under § 73.57(g) until such time that the individual's existing authorization either expires, is terminated, or is otherwise required to be renewed.

Paragraph (b)(4) is revised to relieve NPR licensees from being required to fingerprint an individual if the licensee is reinstating the unescorted access to a granted individual when that individual returns to the same reactor facility, and the unescorted access has not been interrupted for a continuous period of more than 365 days.

Paragraph (b)(5) is revised to provide non-power reactor licensees the discretion not to fingerprint individuals for which fingerprint-based criminal history records checks have been conducted, and for which the criminal history records checks can be transferred to the gaining licensee in accordance with § 73.57(f)(3). This revision allows for reciprocity of fingerprint-based criminal history records checks and grants NPR licensees the same discretion that is currently granted to power reactor licensees.

Paragraph (b)(8) is revised to include NPR licensees to ensure that NPR licensees use the information obtained as part of the criminal history records check solely for the purpose of determining an individual's suitability for unescorted access.

C. § 73.57(c) Prohibitions

Paragraph (c)(1) is revised to include NPR licensees so that the associated prohibitions are provided to individuals seeking unescorted access at non-power reactors.

D. § 73.57(d) Procedures for Processing of Fingerprint Checks

Paragraph (d)(1) is revised to include non-power reactor facilities so that the established fingerprint provisions and forms that the NRC currently uses for other licensees can be used by NPR licensees.

Paragraph (d)(3)(ii) is revised to apply the application fee provisions to all licensees (including NPR licensees) subject to the § 73.57 fingerprinting requirements.

E. § 73.57(f) Protection of Information

Paragraph (f)(2) is revised to add non-power reactor licensees to ensure that the personal information disclosure restrictions are applied to NPR licensees.

Paragraph (f)(5) is revised to add non-power reactors and thereby provide records retention requirements for the fingerprints and criminal history records checks generated through compliance with revised § 73.57.

F. § 73.57(g) Fingerprinting Requirements for Non-Power Reactor Licensees

Paragraph (g) is added to provide the new fingerprint-based criminal history records checks requirements required by Section 149 of the AEA. The scope of the proposed requirements is consistent with orders on unescorted access issued by the NRC on April 30, 2007, and August 1, 2007 (EA–07–074 and EA–07–098, respectively). These orders require NPR licensees to conduct FBI identification and fingerprint-based criminal history records checks based on fingerprints for individuals granted unescorted access to SNM at these facilities (i.e., an individual who is granted unescorted access could exercise physical control over the special nuclear material possessed by the licensee, which would be of significance to the common defense and security or would adversely affect the health and safety of the public, such that the special nuclear material could be used or removed in an unauthorized manner without detection, assessment, or response by systems or persons designated to detect, assess or respond to such unauthorized use or removal. At NPRs, such individuals include those with the capability and knowledge to use the special nuclear material in the utilization facility or remove the special nuclear material from the utilization facility in an unauthorized manner without detection, assessment, and

response by the physical protection system or related provisions or persons). The orders were issued as interim measures until the NRC could formulate generically applicable requirements for incorporation into NRC regulations.

Paragraph 73.57(g)(1) establishes requirements that prohibit any person from having unescorted access to a non-power reactor facility unless that person has been determined by the licensee to be trustworthy and reliable. This determination is made by an NRC-approved reviewing official who may undertake more extensive background investigations as they deem necessary in order to determine trustworthiness and reliability. The reviewing official is required to have unescorted access in accordance with the requirements of § 73.57, or access to SGI. The licensee's NRC-approved reviewing official evaluates the criminal history records check information to determine whether the individual has a record of criminal activity that indicates that the individual should be denied unescorted access. For each determination of unescorted access, which includes a review of criminal history information, the NRC expects NPR licensees to document the basis for the decision. When negative information is discovered that was not provided by the individual, or which is different in any material respect from the information provided by the individual, this information would be considered, and actions taken based on these findings. The NRC expects these findings to be documented. A criminal history record containing a pattern of behaviors which could be expected to recur or continue, or recent behaviors which cast questions on whether an individual should have unescorted access in accordance with § 73.57(g) should be carefully evaluated before unescorted access is granted to the individual.

Paragraph 73.57(g)(2)(i) establishes requirements for NPR licensees to obtain fingerprints for criminal history records checks for each individual who is seeking or permitted unescorted access to ''vital areas'' of the non-power reactor facility. ''Vital area'' is defined in § 73.2 as ''any area which contains vital equipment,'' and ''vital equipment'' is in turn defined in § 73.2 as ''any equipment, system, device, or material, the failure, destruction, or release of which could directly or indirectly endanger the public health and safety by exposure to radiation. Equipment or systems which would be required to protect public health and safety following such failure, destruction, or releases are also considered to be vital.'' For a small number of licensees, the vital area criterion may increase the scope of personnel required to obtain fingerprinting beyond the SNM criterion proposed in § 73.57(g)(2)(ii). A ''vital area'' at a particular NPR will vary as a function of the facility design. Security assessments have been performed by the NRC for a number of licensees that can provide the licensees insight into what constitutes a ''vital area.''

In response to unescorted access orders issued by the NRC on April 30, 2007, and August 1, 2007 (EA–07–074 and EA–07–098, respectively), licensees developed procedures for granting unescorted access to their facilities. These procedures included conducting FBI identification and fingerprint-based criminal history records checks for individuals who requested, or were already granted, unescorted access to special nuclear material (SNM) at these facilities. The orders defined an individual who is granted unescorted access as one who could exercise physical control over the SNM possessed by the licensee, which would be of significance to the common defense and security or would adversely affect the health and safety of the public, such that the SNM could be used or removed in an unauthorized manner without detection, assessment, or response by systems or persons designated to detect, assess or respond to such unauthorized use or removal.

While the rule still requires those requesting access to SNM undergo FBI fingerprint-based criminal history records checks, it also establishes requirements for NPR licensees to obtain fingerprints for criminal history records checks for each individual who is seeking or permitted unescorted access to ''vital areas'' of the NPR facility. The addition of the vital area criterion only affects licensees that have a vital area, as described in § 73.2, at their facility. For the majority of licensees, implementing this rule will not require any actions in addition to their current security plans and procedures, thereby making this a seamless implementation for those licensees.

Paragraph (g)(2)(ii) establishes requirements for NPR licensees to obtain fingerprints for criminal history records checks for each individual who is seeking or granted unescorted access to SNM in the non-power reactor facility. This provision is consistent with the criteria used in the unescorted access order. The Commission notes that there may be significant overlap between the two criteria (i.e., SNM and vital area) of proposed § 73.57(g)(2). As an example, SNM can be considered to be vital equipment under the material portion of the § 73.2 vital equipment definition. The NRC expects that the SNM criterion would, in most situations, determine whether an individual is required to be fingerprinted in accordance with the proposed provisions.

It is not the intent of the SNM criterion to cause individuals to be fingerprinted without the consideration of the potential safety significance of the material. Instead, fingerprinting individuals for unescorted access to SNM should be limited to SNM which would be of significance to the common defense and security or could adversely affect the health and safety of the public. When determining what SNM meets this criterion, NPR licensees should consult their security plans and procedures and inform this decision with existing security assessments. Typically, SNM that meets this criterion would be strategic SNM, SNM of moderate strategic significance, or SNM of low strategic significance, as defined in § 73.2. It is not the NRC's intent to fingerprint individuals who wish to have unescorted access to minute amounts of SNM and do not meet these criteria.

For both §§ 73.57(g)(2)(i) and (ii), for the purposes of determining which individuals must be fingerprinted, an individual must additionally (beyond simply seeking unescorted access) possess the capability and knowledge to make unauthorized use of the special nuclear material in the non-power reactor. This constraint in the requirement may limit the requirement for application of fingerprint-based criminal history records checks. In some cases, more than simple physical access to special nuclear material or specified areas is necessary to require licensees to obtain fingerprint-based criminal history records checks under §§ 73.57(g)(2)(i) and (ii). To determine which individuals should be fingerprinted for unescorted access, NPR licensees need to evaluate their current security plans and procedures considering the definition of vital area (in 10 CFR part 73) and the requirements of §§ 73.57(g)(2)(i) and (ii), as well as any other security assessment information that might be available. For example, an NPR licensee may decide for practical reasons to fingerprint individuals who wish to have unescorted access within the controlled access area.

In most cases, the provisions of § 73.57(g) use an NPR licensee's procedures similar to those used to implement the previous unescorted access and SGI access fingerprinting

orders and rulemaking (73 FR 63546; October 24, 2008). More importantly, these provisions of § 73.57 follow the regulatory processing and handling requirements already incorporated into § 73.57.

When a licensee submits fingerprints to the NRC under these provisions, the licensee will receive a criminal history review, provided in Federal records, since the individual's eighteenth birthday. The licensee's reviewing official shall evaluate the criminal history record information pertaining to the individual as required by revised § 73.57(g). The criminal history records checks shall be used in the determination of whether the individual has a record of criminal activity that indicates that the individual should not have unescorted access at the non-power reactor facility. Each determination of unescorted access includes a review of the fingerprint-based criminal history records information and shall include the licensee's documentation of the basis for the decision.

1. When negative information is discovered that was not provided by the individual, or that is different in any material respect from the information provided by the individual, this information shall be considered, and actions taken based on these findings shall be documented.

2. A record containing a pattern of behaviors that indicates that the behaviors could be expected to recur or continue, or recent behaviors that cast questions on whether an individual should have unescorted access in accordance with the proposed provisions, would be carefully evaluated prior to any authorization of unescorted access.

V. Availability of Documents

The NRC is making the documents identified in the following table available to interested persons through the methods identified. Please see the **ADDRESSES** section of this document for more information.

Document	PDR	ADAMS	Web
EA–07–074, Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Research and Test Reactors, issued April 30, 2007 (72 FR 25337; May 4, 2007).	X	ML070750140	X
EA–07–098, Issuance of Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to the General Atomics Research and Test Reactors, issued August 1, 2007 (72 FR 44590; August 8, 2007).	X	ML072050494	X
Advance Notice of Proposed Rule, published on April 14, 2009 (74 FR 17115)	X	ML090920147	X
Proposed Rulemaking, published on July 20, 2010 (75 FR 42000)	X	ML100610314	X
Proposed Rule, reopening of public comment period published on December 20, 2010 (75 FR 79312).	X	ML103410299	X
Regulatory Analysis	X	ML111310119	X
Regulatory Analysis Appendix	X	ML111310122	X
Final Rule Information Collection Analysis	X	ML111310115	X

VI. Criminal Penalties

For the purpose of Section 223 of the AEA, the Commission amends 10 CFR part 73 under Sections 149 of the AEA. Willful violations of the rule will be subject to criminal enforcement.

VII. Agreement State Compatibility

Under the Policy Statement on Adequacy and Compatibility of Agreement States Programs, approved by the Commission on June 20, 1997, and published in the **Federal Register** (62 FR 46517; September 3, 1997), this rule is classified as compatibility ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of this chapter. Although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements by a mechanism that is consistent with the particular State's administrative procedure laws. Category ''NRC'' regulations do not confer regulatory authority on the State.

VIII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. The NRC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

IX. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. The NRC is not aware of any voluntary consensus standard that could be used instead of the Government-unique standards.

X. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A, National Environmental Policy Act; Regulations Implementing Section 102(2), of 10 CFR part 51, Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions, that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action.

XI. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget (OMB), approval number 3150–0002.

The burden to non-power reactors for the information collections associated with unescorted access to vital areas is estimated to average 2.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T–5 F53), U.S. Nuclear

Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail to *Infocollects.Resource@nrc.gov;* and to the Desk Officer, Chad Whiteman, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0002), Office of Management and Budget, Washington, DC 20503. You may also email comments to *Chad_S_Whiteman@omb.eop.gov* or comment by telephone at 202–395–4718.

XII. Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XIII. Regulatory Analysis: Availability

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. An opportunity for public comment on the regulatory analysis was published in the **Federal Register** on July 20, 2010 (73 FR 42000). Availability of the regulatory analysis is indicated in the preamble of this final rule document within the Availability of Documents table in Section V of this document.

XIV. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of non-power reactors. Only one of the companies and universities that own and operate these facilities falls within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810), and the economic impact on this entity is judged to be small.

XV. Backfit Analysis

The NRC's backfit provisions are found in the regulations at 10 CFR 50.109, 70.76, 72.62, and 76.76, and its issue finality provisions are located in 10 CFR part 52. Under § 50.2, non-power reactors are research or test reactors licensed in accordance with Sections 103 or 104.c of the AEA and 10 CFR 50.21(c) or 50.22 for research and development. Accordingly, the backfit provisions of 10 CFR part 50 would be the only backfit provision potentially implicated by the licensing of test, research, or training reactors. The NRC has determined that the backfit provisions in § 50.109 do not apply to test, research, or training reactors because the rulemaking record for § 50.109 indicates that the Commission intended to apply this provision to only power reactors, and NRC practice has been consistent with this rulemaking record. The 10 CFR part 52 issue finality provisions do not apply to test, research, or training reactors because these reactors are not licensed under 10 CFR part 52. Therefore, a backfit analysis was not prepared for this final rule.

XVI. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the OMB.

List of Subjects in 10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 73.

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

■ 1. The authority citation for 10 CFR part 73 continues to read as follows:

Authority: Secs. 53, 161, 149, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2169, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 594 (2005).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99–399, 100 Stat. 876 (42 U.S.C. 2169).

■ 2. In § 73.57:

■ a. The section heading, paragraphs (a), (b)(1), (b)(2)(i), the introductory text of paragraph (b)(4), paragraphs (b)(4)(i), (b)(5), (b)(8), the introductory text of paragraph (c)(1), and paragraphs (d)(1), (d)(3)(ii), (f)(2), and (f)(5) are revised; and

■ b. paragraphs (b)(2)(v) and (g) are added.

The revisions and additions read as follows:

§ 73.57 Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information.

(a) *General.*

(1) Each licensee who is authorized to engage in an activity subject to regulation by the Commission shall comply with the requirements of this section.

(2) Each applicant for a license to engage in an activity subject to regulation by the Commission, as well as each entity who has provided written notice to the Commission of intent to file an application for licensing, certification, permitting, or approval of a product subject to regulation by the Commission shall submit fingerprints for those individuals who will have access to Safeguards Information.

(3) Before receiving its operating license under 10 CFR part 50 or before the Commission makes its finding under § 52.103(g) of this chapter, each applicant for a license to operate a nuclear power reactor (including an applicant for a combined license) or a non-power reactor may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility or non-power reactor facility.

(b) * * *

(1) Except those listed in paragraph (b)(2) of this section, each licensee subject to the provisions of this section shall fingerprint each individual who is permitted unescorted access to the nuclear power facility, the non-power reactor facility in accordance with paragraph (g) of this section, or access to Safeguards Information. The licensee will then review and use the information received from the Federal Bureau of Investigation (FBI) and, based on the provisions contained in this section, determine either to continue to grant or to deny further unescorted access to the nuclear power facility, the non-power reactor facility, or access to Safeguards Information for that individual. Individuals who do not have unescorted access or access to Safeguards Information shall be fingerprinted by the licensee and the results of the criminal history records check shall be used before making a determination for granting unescorted access to the nuclear power facility, non-power reactor facility, or to Safeguards Information.

(2) * * *

(i) For unescorted access to the nuclear power facility or the non-power reactor facility (but must adhere to provisions contained in §§ 73.21 and 73.22): NRC employees and NRC contractors on official agency business; individuals responding to a site emergency in accordance with the provisions of § 73.55(a); offsite emergency response personnel who are responding to an emergency at a non-power reactor facility; a representative of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement at designated facilities who has been certified by the NRC; law enforcement personnel acting in an official capacity; Federal, State or local government employees who have had equivalent reviews of FBI criminal history data; and individuals employed at a facility who possess ''Q'' or ''L'' clearances or possess another active government granted security clearance (i.e., Top Secret, Secret, or Confidential);

* * * * *

(v) Individuals who have a valid unescorted access authorization to a non-power reactor facility on November 7, 2012 are not required to undergo a new fingerprint-based criminal history records check pursuant to paragraph (g) of this section, until such time that the existing authorization expires, is terminated, or is otherwise to be renewed.

* * * * *

(4) Fingerprinting is not required if the licensee is reinstating the unescorted access to the nuclear power facility, the non-power reactor facility, or access to Safeguards Information granted an individual if:

(i) The individual returns to the same nuclear power utility or non-power reactor facility that granted access and such access has not been interrupted for a continuous period of more than 365 days; and

* * * * *

(5) Fingerprints need not be taken, in the discretion of the licensee, if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to a nuclear power facility, a non-power reactor facility, or to Safeguards Information by another licensee, based in part on a criminal history records check under this section. The criminal history records check file may be transferred to the gaining licensee in accordance with the provisions of paragraph (f)(3) of this section.

* * * * *

(8) A licensee shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access to the nuclear power facility, the non-power reactor facility, or access to Safeguards Information.

(c) * * *

(1) A licensee may not base a final determination to deny an individual unescorted access to the nuclear power facility, the non-power reactor facility, or access to Safeguards Information solely on the basis of information received from the FBI involving:

* * * * *

(d) * * *

(1) For the purpose of complying with this section, licensees shall, using an appropriate method listed in § 73.4, submit to the NRC's Division of Facilities and Security, Mail Stop TWB 05B32M, one completed, legible standard fingerprint card (Form FD–258, ORIMDNRCOOOZ) or, where practicable, other fingerprint records for each individual requiring unescorted access to the nuclear power facility, the non-power reactor facility, or access to Safeguards Information, to the Director of the NRC's Division of Facilities and Security, marked for the attention of the Division's Criminal History Check Section. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by calling 301–415–5877, or by email to *FORMS.Resource@nrc.gov*. Guidance on what alternative formats might be practicable is referenced in § 73.4. The licensee shall establish procedures to ensure that the quality of the fingerprints taken results in minimizing the rejection rate of fingerprint cards due to illegible or incomplete cards.

* * * * *

(3) * * *

(ii) The application fee is the sum of the user fee charged by the FBI for each fingerprint card or other fingerprint record submitted by the NRC on behalf of a licensee, and an administrative processing fee assessed by the NRC. The NRC processing fee covers administrative costs associated with NRC handling of licensee fingerprint submissions. The Commission publishes the amount of the fingerprint records check application fee on the NRC public Web site. (To find the current fee amount, go to the Electronic Submittals page at *http://www.nrc.gov/site-help/e-submittals.html* and see the link for the Criminal History Program.) The Commission will directly notify licensees who are subject to this regulation of any fee changes.

* * * * *

(f) * * *

(2) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his/her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to the nuclear power facility, the non-power reactor facility or access to Safeguards Information. No individual authorized to have access to the information may re-disseminate the information to any other individual who does not have a need to know.

* * * * *

(5) The licensee shall retain all fingerprint and criminal history records received from the FBI, or a copy if the individual's file has been transferred, on an individual (including data indicating no record) for one year after termination or denial of unescorted access to the nuclear power facility, the non-power reactor facility, or access to Safeguards Information.

(g) *Fingerprinting requirements for unescorted access for non-power reactor licensees.*

(1) No person shall be permitted unescorted access to a non-power reactor facility unless that person has been determined by an NRC-approved reviewing official to be trustworthy and reliable based on the results of an FBI fingerprint-based criminal history records check obtained in accordance with this paragraph. The reviewing official is required to have unescorted access in accordance with this section or access to Safeguards Information.

(2) Each non-power reactor licensee subject to the requirements of this section shall obtain the fingerprints for a criminal history records check for each individual who is seeking or permitted:

(i) Unescorted access to vital areas of the non-power reactor facility; or

(ii) Unescorted access to special nuclear material in the non-power reactor facility provided the individual who is seeking or permitted unescorted access possesses the capability and knowledge to make unauthorized use of the special nuclear material in the non-power reactor facility or to remove the special nuclear material from the non-power reactor in an unauthorized manner.

Dated at Rockville, Maryland, this 4th day of May 2012.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2012–11293 Filed 5–10–12; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM11–20–000; Order No. 763]

Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: Under section 215 of the Federal Power Act (FPA), the Federal Energy Regulatory Commission (Commission) approves Reliability Standards PRC–006–1 (Automatic Underfrequency Load Shedding) and EOP–003–2 (Load Shedding Plans), developed and submitted to the Commission for approval by the North American Electric Reliability Corporation (NERC), the Electric Reliability Organization certified by the Commission. In addition, pursuant to section 215(d)(5) of the FPA, the Commission directs NERC to develop a modification to clarify the intent of one provision of the Reliability Standard. The approved Reliability Standards establish design and documentation requirements for automatic underfrequency load shedding programs that arrest declining frequency and assist recovery of frequency following system events leading to frequency degradation. The Commission approves, with modifications, the related Violation Risk Factors and Violation Severity Levels, implementation plan, and effective date proposed by NERC. The Commission also approves the regional variance for the Western Electricity Coordinating Council in Reliability Standard PRC–006–1.

DATES: *Effective Date:* This rule will become effective July 10, 2012.

FOR FURTHER INFORMATION CONTACT:

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Matthew Vlissides (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8408, *Matthew.Vlissides@ferc.gov*.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Jon Wellinghoff, Chairman; Philip D. Moeller, John R. Norris.

Final Rule

Issued May 7, 2012.

1. Under section 215 of the Federal Power Act (FPA),[1] the Commission approves Reliability Standards PRC–006–1 (Automatic Underfrequency Load Shedding) and EOP–003–2 (Load Shedding Plans). In addition, pursuant to section 215(d)(5) of the FPA, the Commission directs the North American Electric Reliability Corporation (NERC) to develop a modification to clarify the intent of one provision of the Reliability Standard. The approved Reliability Standards were developed and submitted for approval to the Commission by NERC, the Commission certified Electric Reliability Organization (ERO) responsible for developing and enforcing mandatory Reliability Standards. The approved Reliability Standards establish design and documentation requirements for automatic underfrequency load shedding (UFLS) programs, which are meant to arrest declining frequency and assist recovery of frequency following underfrequency events and provide last resort system preservation measures.

2. The Commission approves, with modifications, the related Violation Risk Factors (VRFs) and Violation Severity Levels (VSLs), implementation plan, and effective date proposed by NERC. The Commission approves the retirement of the currently-effective Reliability Standards PRC–007–0, PRC–009–0, and EOP–003–1, and the NERC-approved Reliability Standard PRC–006–0. Further, the Commission approves the regional variance for the Western Electricity Coordinating Council (WECC) in PRC–006–1.

I. Background

A. Mandatory Reliability Standards

3. Section 215 of the FPA requires a Commission-certified ERO to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.[2]

4. Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO[3] and, subsequently, certified NERC as the ERO.[4] On March 16, 2007, the Commission issued Order No. 693, approving 83 of the 107 Reliability Standards filed by NERC, including Reliability Standards PRC–007–0, PRC–009–0, and EOP–003–1.[5] The Commission neither approved nor remanded NERC-approved Reliability Standard PRC–006–0 in Order No. 693,[6] which required regional reliability organizations to develop, coordinate, document and assess UFLS program design and effectiveness at least every five years. The Commission determined neither to approve nor remand this ''fill-in-the-blank'' Reliability Standard because the regional procedures had not been submitted, and the Commission held that it would not propose to approve or remand PRC–006–0 until the ERO submitted the additional information.[7]

B. NERC Petition

5. On March 31, 2011, NERC filed a petition seeking Commission approval of Reliability Standards PRC–006–1 (Automatic Underfrequency Load Shedding) and EOP–003–2 (Load Shedding Plans), and the concurrent retirement of the currently-effective Reliability Standards PRC–007–0, PRC–009–0, and EOP–003–1, and the NERC-approved Reliability Standard PRC–006–0. The petition, as amended on May 17, 2011, states that PRC–006–1 establishes design and document requirements for UFLS programs that arrest declining frequency and assist recovery of frequency following system events leading to frequency degradation.[8] The petition states that EOP–003–2 makes minimal changes to EOP–003–1 by removing references to UFLS, which NERC describes as

[1] 16 U.S.C. 824o (2006).

[2] 16 U.S.C. 824o(e).

[3] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. ¶ 31,204, *order on reh'g,* Order No. 672–A, FERC Stats. & Regs. ¶ 31,212 (2006).

[4] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[5] *Mandatory Reliability Standards for the Bulk-Power System,* Order No. 693, FERC Stats. & Regs. ¶ 31,242, at P 603, *order on reh'g,* Order No. 693–A, 120 FERC ¶ 61,053 (2007).

[6] *Id.* P 1479.

[7] *Id.* PP 1477, 1479.

[8] The Notice of Proposed Rulemaking in this docket included a primer on UFLS programs generally. *Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards,* Notice of Proposed Rulemaking, 76 Fed. Reg. 66,220 (October 26, 2011), FERC Stats. & Regs. ¶ 32,682 (2011).

redundant in light of PRC–006–1, and instead focuses EOP–003–2 on undervoltage conditions.

6. The petition states that Reliability Standard PRC–006–1 achieves a specific reliability goal by establishing design and documentation requirements for automatic UFLS programs to arrest declining frequency, assist recovery of frequency following underfrequency events, and provide last resort system preservation measures. Further, the petition states that PRC–006–1 contains a technically sound method to achieve its reliability goal by establishing a framework for developing, designing, assessing and coordinating UFLS programs, and that PRC–006–1 is clear and unambiguous regarding what is required and who is required to comply with the Reliability Standard.

7. In the petition, NERC proposes VRFs and VSLs, an implementation plan, and an effective date. The petition requests an effective date for Reliability Standards PRC–006–1 and EOP–003–2 of one year following the first day of the first calendar quarter after applicable regulatory approvals with respect to all Requirements of the Reliability Standards *except* Parts 4.1 through 4.6 of Requirement R4 of PRC–006–1. With respect to Parts 4.1 through 4.6 of Requirement R4 of PRC–006–1, NERC requests an effective date of one year following the receipt of the generation data that would be required in draft Reliability Standard PRC–024–1 [9] but no sooner than one year following the first day of the first calendar quarter after applicable regulatory approvals of PRC–006–1.

C. Notice of Proposed Rulemaking

8. On October 20, 2011, the Commission issued a Notice of Proposed Rulemaking (NOPR) proposing to approve Reliability Standards PRC–006–1 and EOP–003–2 as just, reasonable, not unduly discriminatory or preferential, and in the public interest. The Commission proposed to approve PRC–006–1 and EOP–003–2 because the UFLS program addressed in the Reliability Standards is important to arresting declining frequency and assisting recovery of frequency following system events that lead to system instability, which can result in a blackout. The NOPR stated that the Reliability Standards are necessary for reliability because UFLS is used in extreme conditions to stabilize the balance between generation and load after an electrical island has been formed, dropping enough load to allow frequency to stabilize within the island. The NOPR concluded that PRC–006–1, in conjunction with the conforming changes to EOP–003–2, provides last resort Bulk-Power System preservation measures by establishing the first national Reliability Standard of common performance characteristics that all UFLS programs must meet.

9. The NOPR proposed to approve the related VRFs and VSLs, implementation plan, and effective date proposed by NERC. The NOPR also proposed to approve the regional variance for WECC in Reliability Standard PRC–006–1.

10. While proposing to approve Reliability Standards PRC–006–1 and EOP–003–2, the NOPR addressed or sought comments on the following issues: (A) Impact of resources not connected to the bulk electric system; (B) validation of power system models used to simulate UFLS programs; (C) scope of UFLS events assessments; (D) impact of generator owner trip settings outside of the UFLS program; (E) UFLS program coordination with other protection systems; (F) identification of island boundaries in UFLS programs; (G) automatic load shedding in PRC–006–1 and manual load shedding in EOP–003–2; (H) elimination of balancing authority responsibilities in EOP–003–2; and (I) the ''Lower VSL'' for Requirement R8 and the ''Medium'' VRF for Requirement R5 of PRC–006–1.

11. In response to the NOPR, comments were filed by NERC and 12 interested persons.[10] The comments generally support the approval of Reliability Standards PRC–006–1 and EOP–003–2. The comments also provide information responsive to the questions raised in the NOPR. In the discussion below, we address the questions raised in the NOPR in light of the comments.

II. Discussion

12. The Commission approves Reliability Standards PRC–006–1 and EOP–003–2 as just, reasonable, not unduly discriminatory or preferential, and in the public interest. The Commission's approval is consistent with the broad support for the Reliability Standards expressed in the comments. The UFLS program addressed in Reliability Standard PRC–006–1 is important to arresting declining frequency and assisting recovery of frequency following system events that lead to system instability, which can result in a blackout. Accordingly, the Reliability Standard is necessary for reliability because UFLS is used in extreme conditions to stabilize the balance between generation and load after an electrical island has been formed, dropping enough load to allow frequency to stabilize within the island. PRC–006–1, in conjunction with the conforming changes to EOP–003–2, provides last resort Bulk-Power System preservation measures by establishing the first national Reliability Standard of common performance characteristics that all UFLS programs must meet. For the same reasons, we approve the regional variance for WECC in PRC–006–1. We also approve the VRFs and VSLs designated for the requirements of the Reliability Standards, with modifications, and the implementation plan and effective date, as proposed by NERC.

13. We address below the following issues raised in the NOPR in light of the comments received: (A) Impact of resources not connected to the bulk electric system; (B) validation of power system models used to simulate UFLS programs; (C) scope of UFLS events assessments; (D) impact of generator owner trip settings outside of the UFLS program; (E) UFLS program coordination with other protection systems; (F) identification of island boundaries in UFLS programs; (G) automatic load shedding in PRC–006–1 and manual load shedding in EOP–003–2; (H) elimination of balancing authority responsibilities in EOP–003–2; and (I) the ''Lower VSL'' for Requirement R8 and the ''Medium'' VRF for Requirement R5 of PRC–006–1. Regarding the last issue, the Commission directs NERC to modify the ''Lower VSL'' for Requirement R8 of PRC–0061 and the ''Medium'' VRF for Requirement R5 of PRC–006–1 consistent with the discussion below.

A. Impact of Resources Not Connected to Bulk Electric System Facilities

14. Requirement R2 of Reliability Standard PRC–006–1 requires planning coordinators to identify islands to serve as a basis for designing UFLS programs. Requirement R3 addresses performance characteristics for UFLS programs. Requirement R4 requires each planning coordinator to conduct and document the assessment of its UFLS design and determine if the UFLS program meets the performance characteristics in Requirement R3 for each island identified in Requirement R2. The simulations outlined in Requirement R4 all concern individual generating units greater than 20 MVA gross nameplate rating or generating plants/facilities greater then 75 MVA ''connected to the bulk electric system.''

[9] Draft Reliability Standard PRC–024–1 addresses ''Generator Performance During Frequency and Voltage Excursions'' and is currently being developed in the NERC standard drafting process.

[10] A list of the commenters is provided in the Appendix.

15. In the NOPR, the Commission stated that some generation meeting the 20 MVA and 75 MVA criteria in Reliability Standard PRC–006–1, Requirement R4 would not be modeled pursuant to Requirement R4 because it is not connected to bulk electric system facilities. The Commission explained that a resource not directly connected to the bulk electric system may serve load designed to be shed in a UFLS program. The Commission expressed concern that failure to account for resources not directly connected to the bulk electric system could result in planning coordinators being unaware of how those resources respond to underfrequency conditions. The Commission stated that if a planning coordinator is unaware of how these resources respond, it may plan to shed more load than is necessary for an area's frequency to return to normal, which could cause an unintended overfrequency condition if the plan is carried out in the operating timeframe. These conditions, in turn, could cause the UFLS program to violate the performance characteristics specified in Requirement R3 of PRC–006–1. The Commission sought comment as to whether and how all resources required for the reliable operation of the bulk electric system, including resources not connected to bulk electric system facilities, are considered in the development of UFLS programs under Requirements R3 and R4 of PRC–006–1.

Comments

16. NERC agrees with the NOPR that failing to model qualifying generation not directly connected to the bulk electric system could affect the simulated frequency response. NERC, however, clarifies that Reliability Standard PRC–006–1 does not ''establish parameters for what resources are modeled in [] simulations'' and that ''power system models used in UFLS assessments are generally the same models used in transmission planning assessments, which include models of all generation units and plants that meet the threshold size requirements even those not connected directly to the Bulk Electric System.'' [11] In addition, NERC states that a standard authorization request is under development as part of the ''second phase'' of the project to revise the definition of bulk electric system, and information developed as part of that project could be used to assess whether any changes are needed to PRC–006–1.

17. EEI, TAPS, MISO, and FRCC maintain that the vast majority of qualifying generation is accounted for in Reliability Standard PRC–006–1. EEI comments that bulk electric system resources account for the ''vast majority of resources within all interconnections'' and supports the standard drafting team's belief that the Reliability Standard generally captures about 95 percent of utility-owned installed capacity.[12] While EEI acknowledges that there are a small number of unaccounted for generation resources that meet the qualifying criteria, EEI comments that what is captured is sufficient for assessing reliable operation of the bulk electric system. EEI also maintains that planning coordinators already consider other resources as appropriate.

18. TAPS states that the ''great majority'' of generators are not set to trip before the underfrequency set points, so they will be available for UFLS programs.[13] TAPS contends that the only generators of concern are those that: (1) Do not meet Reliability Standard PRC–006–1's size and connection criteria; (2) trip prior to underfrequency set points; and (3) are dispatched during underfrequency events because they are not required to be modeled under PRC–006–1. TAPS maintains that the number of generators that meet these criteria is ''very small'' so that modeling them would have an ''infinitesimal reliability benefit,'' not improving the overall accuracy of the UFLS program design and not justifying the additional costs.[14]

19. MISO states that UFLS simulations should not be required to include all generation that meets the 20 MVA and 75 MVA criteria in Reliability Standard PRC–006–1, Requirement R4. MISO cites the standard drafting team's belief that PRC–006–1 captures about 95 percent of utility-owned installed capacity.[15] MISO also maintains that the standard drafting team deserves deference and that simulations will always contain some degree of uncertainty.

20. FRCC states that generators that fall within the size requirements of Reliability Standard PRC–006–1 but that are not connected to bulk electric system facilities constitute a ''very small amount.'' [16] FRCC maintains that this amount is well below the error tolerance of a well-designed UFLS program and, thus, is not important.

21. SWPA states that planning coordinators, in developing UFLS programs, should consider all resources that are determined to be required for the reliable operation of the bulk electric system, regardless of whether those resources are directly connected to the bulk electric system.

22. NYISO comments that it analyzes UFLS effectiveness using a Multiregional Modeling Working Group dynamics model of the Eastern Interconnection, which includes all resources on the system regardless of bulk electric system connections.

Commission Determination

23. In the NOPR, the Commission expressed concern regarding the development of UFLS programs that fail to account for qualifying generation not directly connected to the bulk electric system. We are satisfied with the explanations provided by commenters. First, we are persuaded by NERC's explanation that Reliability Standard PRC–006–1 does not limit the resources that can be modeled in the UFLS assessments and that power system models used in UFLS assessments generally model all qualifying generation, including resources not directly connected to the bulk electric system. In summary, although PRC–006–1 does not require all of the generation that is not directly connected to the bulk electric system to be included in the modeling, the subset of these resources that are required to assure that the UFLS models are sufficient to accurately predict system performance will be included. Similarly, we accept comments from EEI, TAPS, MISO, and FRCC that PRC–006–1 requires modeling of the vast majority of qualifying generation to ensure the reliable operation of the bulk electric system.

24. Like SWPA, the Commission believes that requiring all qualifying assets to be accounted for in UFLS programs, regardless of whether they are directly or indirectly connected to the bulk electric system, is useful to ensuring the effectiveness of the programs. Not requiring applicable entities to model sufficient amounts of qualifying generation indirectly connected to the bulk electric system could result in applicable entities not knowing how those resources react during underfrequency situations, which could cause excessive load shedding in an emergency and further contribute to system instability.

25. NERC states in its comments that this issue could be further evaluated in the ''second phase'' of the project to revise the definition of bulk electric system, and that information from that project could be used as a basis for

[11] NERC Comments at 4.

[12] EEI Comments at 2–3.

[13] TAPS Comments at 4.

[14] *Id.* at 4–5.

[15] MISO Comments at 3.

[16] FRCC Comments at 2.

revising Reliability Standard PRC–006–1 if necessary.[17] Without prejudging those efforts, the Commission will not issue a directive requiring the modeling of qualifying generation not directly connected to the bulk electric system.

B. Validation of Power System Models

26. In the NOPR, the Commission stated that dynamic simulations that fail to accurately represent the power system can result in UFLS programs that are ineffective. The Commission, however, concluded that the UFLS program design requirements established in Requirement R2 of Reliability Standard PRC–006–1 and the required assessments established in Requirements R4 and R11 of PRC–006–1 are generally acceptable and include improvements over the current Reliability Standards.

Comments

27. FRCC comments that improving the accuracy of power system models used in simulating system response to forecasted system conditions is an appropriate goal, but achieving 100 percent accuracy is not practicable. EEI comments that dynamic simulations for any large power system will never be 100 percent accurate and asks the Commission not to impose any new directives which might unnecessarily increase costs to industry.

28. NYISO states that a lack of accuracy in modeling can have a significant impact on analyses of under-generated islands. Specifically, NYISO states that ''optimistic models of unit governing response can lead to invalid conclusions regarding minimum frequency and frequency recovery.'' [18] NYISO indicates that it is taking steps to improve the accuracy of modeling frequency recovery by, among other things, aligning the dynamics model to observed system response.

Commission Determination

29. The Commission accepts the comments from EEI and FRCC that power system models with 100 percent accuracy are not practicable. The Commission, however, is mindful of the consequences of inaccurate power system models and their impact on an entity's ability to accurately simulate system performance. As noted by NYISO, inaccurate models can lead to invalid conclusions which can be detrimental to the analysis and operation of the bulk electric system. At a minimum, the models should accurately predict system performance during UFLS events. Although entities may take additional steps, such as the step taken by NYISO to ensure accurate models, as stated in the NOPR, the Commission believes that the design requirements in Reliability Standard PRC–006–1 are acceptable.[19]

C. UFLS Event Assessments

1. Assessments in the Absence of Island Formation

30. Requirement R11 of Reliability Standard PRC–006–1 requires planning coordinators to conduct assessments after a ''BES islanding event results in system frequency excursion below the initializing set points of the UFLS program.''

31. In the NOPR, the Commission expressed concern that the phrase ''BES islanding event'' could be interpreted to mean that a planning coordinator only has to assess an event if it meets both of the following requirements: (1) System frequency excursions fall below the initializing set point for UFLS; and (2) bulk electric system islands form within the Interconnection. The Commission explained that, if frequency falls below the initializing UFLS set point but islands do not form (e.g., because the event was not severe enough to isolate portions of the Interconnection, or UFLS or other protection systems failed to operate properly to form islands), an assessment of the performance of the UFLS program for this event is still useful because it can determine if the UFLS program operated as expected. The Commission sought comment on what actions must planning coordinators take under Requirement R11 of PRC–006–1 if an event results in system frequency excursions falling below this initializing set point for UFLS but without the formation of a bulk electric system island.

Comments

32. In its comments, NERC states that ''[a]lthough PRC–006–1 does not prescribe an analysis for [the non-islanding scenario identified in the NOPR], activating UFLS during an Interconnection-wide event would involve a significant loss of generation and analysis would be performed under the NERC Event Analysis program or the NERC Rules of Procedure, depending on the severity of the event.'' [20] NERC further states that the ''activation of UFLS, while highly unlikely, would be a significant event requiring assessment of several aspects of system frequency, including system Frequency Response, equipment performance, and coordination of protection and control systems, in addition to the assessment of UFLS program operation.'' [21] Ultimately, NERC agrees that an assessment of the performance of UFLS, even in the absence of island formation, is useful.

33. EEI and MISO agree with NERC that Requirement R11 of Reliability Standard PRC–006–1 requires both conditions (i.e., frequency excursion and islanding) to be met. MISO agrees with the NOPR that an analysis of excursions without islanding is useful. However, MISO and EEI comment that such an analysis is outside the scope of the Reliability Standard. MISO, quoting the NOPR, states that UFLS ''is designed for use in extreme conditions to stabilize the balance between generation and load after an electrical island has been formed.'' [22] Accordingly, MISO argues that a UFLS program ''can only truly be assessed in light of its performance after an island has formed.'' [23] In addition, such assessments are costly, time consuming and resource intensive, according to MISO. EEI maintains that entities ''broadly perform assessments of lesser events as they deem necessary.'' [24] EEI contends that such assessments are not required in PRC–006–1 because ''to do so would go beyond the intent of the program which is the design of UFLS programs.'' [25] Instead, EEI notes that applicable entities normally conduct operational assessments regularly, and if an entity identifies a problem the entity would report the matter as a misoperation with an obligation to remediate. EEI also points to the draft NERC Event Analysis Process [26] and its application to what EEI describes as ''underfrequency events of a lesser level'' (i.e., events resulting in load shedding with a loss of load of 100 MW or more).[27] EEI contends that the Commission's concerns regarding analysis of lesser events will be satisfied once the NERC Event Analysis Process is finalized.

34. SWPA states that it is reasonable for planning coordinators to request and analyze event data in the absence of island formation to assess the performance of UFLS programs. Specifically, SWPA comments that

[17] NERC Comments at 5.

[18] NYISO Comments at 3.

[19] NOPR, FERC Stats & Regs, ¶ 32,682 at P 34.

[20] NERC Comments at 6.

[21] *Id.*

[22] MISO Comments at 4 (*citing* NOPR, FERC Stats & Regs. 32,682 at P 35).

[23] *Id.*

[24] EEI Comments at 5.

[25] *Id.*

[26] We understand the NERC Event Analysis Process to be the same as the NERC Event Analysis program referenced in NERC's comments.

[27] *Id.*

''[t]he assessment of a UFLS event during varying system conditions caused by generator outages, transmission outages, and various maintenance activities, provides an opportunity to discover the impacts of these activities on the expected outcomes described in the plan.'' [28]

Commission Determination

35. NERC clarifies that Requirements R11 and R12 of Reliability Standard PRC–006–1 are triggered when system frequency excursions fall below the initializing set points for UFLS programs and bulk electric system islands form within Interconnections.[29]

36. The Commission agrees with commenters that it would be useful to have an analysis of system frequency excursions to assess the performance of UFLS programs even in the absence of island formation.[30] To that end, we agree with NERC that underfrequency events that result in the initializing of the UFLS set point, even in the absence of island formation, would be analyzed under provisions contained in the NERC Rules of Procedure and the NERC Event Analysis program.[31]

2. Coordination of Assessments and Results

37. Requirements R5 and R13 of Reliability Standard PRC–006–1 provide flexibility in coordinating UFLS design programs and event assessments among planning coordinators whose areas fall within the same island or whose areas are affected by the same event. In the NOPR, the Commission sought comments on whether differences in assessments between planning coordinators should be reported to reliability coordinators for resolution in the event that the process identified in PRC–006–1 does not resolve the differences.

Comments

38. NERC, MISO, and EEI comment that reliability coordinators should not be tasked with resolving differences between planning coordinator event assessments. NERC states that differences between planning coordinator event assessments should not be reported to reliability coordinators because: (1) Reliability coordinator's wide-area view may not coincide with island boundaries; (2) reliability coordinators may have conflicts of interest; (3) reliability coordinators may not have the tools to resolve the differences; and (4) reliability coordinators work in a real-time operating environment, which makes them ill-suited to resolve disputes among planning coordinators.

39. MISO and EEI comment that event assessment differences should not be reported to reliability coordinators because planning coordinators are better positioned to reconcile differences. MISO notes that in some cases where an applicable entity is both a reliability coordinator and planning coordinator (as is the case with MISO), there would be a conflict of interest. Further, MISO maintains that referring disputes to reliability coordinators imposes additional costs with little to no benefit. MISO and EEI also contend that event assessment differences do not pose a risk to the reliability of the bulk electric system, with EEI noting that such differences are ''a result of legitimate engineering and regional practices and processes.'' [32] At most, EEI suggests that reliability coordinators might be used as informal facilitators.

40. SWPA states that a clear resolution process is necessary and that referring disputes to reliability coordinators is a reasonable consideration.

Commission Determination

41. The Commission is persuaded by the comments of NERC, MISO, and EEI that differences between planning coordinator event assessments should not be referred to reliability coordinators for resolution. We share the concern of NERC, MISO, and EEI that referring disputes to reliability coordinators may create conflicts of interest because a planning coordinator may also serve as a reliability coordinator. We agree, however, with SWPA that disputes between planning coordinator event assessments should be resolved. Therefore, the Commission expects planning coordinators to work in good faith including, as appropriate, use of third parties to resolve disputes concerning event assessments. If the Commission finds that these disputes are not being resolved, the Commission may consider adoption of an appropriate process to ensure resolution of the disputes.

3. *Assessment Timeline for Completion*

42. Requirement R11 of Reliability Standard PRC–006–1 requires planning coordinators to perform island event assessments within one year of an event. If the planning coordinator identifies program deficiencies, Requirement R12 of PRC–006–1 requires planning coordinators to conduct and document UFLS design assessments, which are meant to consider the deficiencies, within two years of an event.

43. In the NOPR, the Commission expressed concern that this time frame could be too long because island event assessments and consideration of deficiencies could reasonably be done in a shorter time frame. Moreover, the Commission noted that under PRC–006–1, deficiencies could remain within a UFLS program for two years from an event exposing the Bulk-Power System to instability, uncontrolled separation and cascading outages should a frequency event occur that the UFLS program mishandles. The Commission sought comments on the basis for the two-year time frame and clarification as to how soon after an event would an entity need to implement corrections in response to any deficiencies identified in the event assessment under Requirement R11 of PRC–006–1.

Comments

44. NERC comments that, while some events can be assessed in less time, one year is a realistic time-frame to assess performance for complex events and two years is a realistic time-frame to address identified deficiencies. NERC states that ''the amount of time that a UFLS entity has to implement corrections will be established by the Planning Coordinator, as specified in Requirement R9 of PRC–006–1 * * * [and] [t]he time allotted for corrections will depend on the extent of the deficiencies identified.'' [33]

45. EEI, MISO, and G&T Cooperatives support the timelines in Reliability Standard PRC–006–1. MISO maintains that event assessments are time and resource intensive and must not be rushed. EEI, MISO, and G&T Cooperatives state that planning coordinators can complete analyses of less complex events before the two-year deadline, but they need the maximum

[28] SWPA Comments at 3.

[29] NERC Comments at 6.

[30] NERC Comments at 5; MISO Comments at 4; SWPA Comments at 3.

[31] NERC Comments at 6. Section 807 of the NERC Rules of Procedure addresses ''Analysis of Major Events'' and Section 808 addresses ''Analysis of Off-Normal Events, Potential System Vulnerabilities, and System Performance.'' Separately, the NERC Event Analysis program, which is not incorporated in the NERC Rules of Procedure, as of this time is still under development. Compliance with the NERC Rules of Procedure is mandatory pursuant to section 39.2(b) of the Commission's regulations and is enforceable by the Commission pursuant to section 39.9 of the Commission's regulations. 18 CFR 39.2(b) (''All entities subject to the Commission's reliability jurisdiction under paragraph (a) of this section shall comply with applicable Reliability Standards, the Commission's regulations, and applicable Electric Reliability Organization and Regional Entity Rules made effective under this part.''); 18 CFR 39.9.

[32] EEI Comments at 6.

[33] NERC Comments at 8.

allowable time to finish analyses of complex events. With respect to the time allowed for correcting problems, EEI comments that any deadline in a requirement would be difficult to enforce and would not improve reliability given the variable nature of possible deficiencies.

46. SWPA states that an applicable entity may need to implement corrections that require complex procurement or acquisition processes, and such contracts can be complex, involving many required decisions and actions. Given these complexities, SWPA maintains that four years after event actuation is a reasonable deadline to implement corrections.

Commission Determination

47. Based on the comments, the Commission is persuaded that two years to complete design assessments pursuant to Reliability Standard PRC–006–1 is appropriate. As noted by EEI, MISO, and G&T Cooperatives, assessments of complex events can be time and resource intensive. Thus, we agree that two years is a reasonable maximum allowable time for completion of design assessments. However, we agree with commenters that efforts should be made to complete assessments of less complex events before the two-year maximum allowable period.[34]

48. In response to the Commission's concern that Reliability Standard PRC–006–1 does not specify how soon after an event would an entity need to implement corrections in response to any deficiencies identified in the event assessment under Requirement R11 of PRC–006–1, NERC stated in its comments that:

> The amount of time that a UFLS entity has to implement corrections will be established by the Planning Coordinator, as specified in Requirement R9 of PRC–006–1. The time allotted for corrections will depend on the extent of the deficiencies identified. The schedule specified by the Planning Coordinator will consider the time necessary for budget planning and implementation, recognizing that operating and maintenance budgets normally will not be sufficient to address major revisions and allowances will be necessary for inclusion of approved changes in budgeting cycles.[35]

Requirement R9 of PRC–006–1 states:

> R9. Each UFLS entity shall provide automatic tripping of Load in accordance with the UFLS program design and schedule for application determined by its Planning Coordinator(s) in each Planning Coordinator area in which it owns assets.

[VRF:High][Time Horizon: Long-term Planning]

Notwithstanding NERC's comments, the Commission is not persuaded that Requirement R9 requires corrective action in accordance with a schedule established by the planning coordinator. Based on its comments, however, NERC has expressed no opposition to such a requirement. We accept NERC's comments that Requirement R9 requires a schedule established by the planning coordinator, but NERC's reading of Requirement R9 should be made clear in the Requirement itself. Accordingly, we direct NERC to make that requirement explicit in future versions of the Reliability Standard. Within 30 days of the effective date of this Final Rule, NERC is directed to submit a compliance filing indicating how it plans to comply with this directive and a deadline for compliance.

D. Generator Owner Trip Settings Outside of the UFLS Program

49. In the NOPR, the Commission stated that Requirements 4.1 through 4.7 of Reliability Standard PRC–006–1 are intended to capture the effects of generators that trip prior to UFLS initiation. While agreeing that planning coordinators should consider generators that trip prior to underfrequency set points when developing their UFLS programs, the Commission sought comments on how generation losses outside of the UFLS set points (*i.e.,* generators having trip settings prior to the UFLS underfrequency set points) should be accounted for in UFLS programs (*e.g.,* generator owners who trip outside of the UFLS set points could procure load to shed to account for the loss in generation).

Comments

50. NERC, EEI, TAPS, Dominion, FRCC and EPSA oppose requiring generator owners to procure load to shed for generators that trip outside of the UFLS set points. NERC states that it is appropriate for planning coordinators to consider generators that trip outside of the UFLS set points when designing UFLS programs, but it is inappropriate for planning coordinators to determine whether mitigation is necessary and who will be responsible for providing mitigation.

51. EEI states that Reliability Standard PRC–006–1, Requirement R4 requires that all resources included in the UFLS program that operate outside the specified trip settings be factored in to the dynamic simulation models used to develop the program. EEI further notes that, while there is no formal obligation for generator owners to supply trip setting data to planning coordinators, this information is shared. Unlike modeling generators that trip outside of the UFLS set points, EEI maintains that the issue of procuring load to shed to compensate for such trips is outside the scope of PRC–006–1.

52. TAPS comments that generators that trip prior to underfrequency set points are separately modeled under Reliability Standard PRC–006–1 and that this is the correct approach to account for such generators. TAPS opposes requiring generator owners who trip outside of the UFLS set points to procure load to shed to account for the loss in generation. TAPS objects to a ''one-size-fits all market/contractual solution'' given the absence of a demonstrable reliability problem and the market power concerns it might create.[36] TAPS maintains that in some small islands it may be impossible to procure the necessary load to shed.

53. Dominion states that generator owners whose generators trip prior to UFLS set points should not be required to procure load to shed. Dominion contends that such a scheme could be extremely difficult to design and coordinate, and Dominion is unaware of any distribution provider or transmission owner tariff that offers such a service.

54. FRCC maintains that a small minority of generator underfrequency protection settings are above the minimum UFLS frequency set points and that in many cases any conflicts can be resolved by reexamination of the technical basis for the generator's underfrequency protection. FRCC also states that requiring generator operators to procure load to shed would be technically impossible, and there is no market for compensatory, assignable UFLS to make generator contracts for load shedding feasible.

55. EPSA states that planning coordinators should consider generators that trip prior to underfrequency set points when collecting information and developing their UFLS programs. EPSA maintains, however, that requiring planning coordinators to account for generators that trip prior to the UFLS set points presupposes that there is a material amount of generator losses occurring. EPSA believes that implementation of Reliability Standard PRC–006–1 will allow planning coordinators to gather information to determine the amount of losses, which can then be used to decide whether generator losses need to be accounted for. EPSA states that if generator losses are found to be a material concern that

[34] EEI Comments at 7; MISO Comments at 6.

[35] NERC Comments at 8.

[36] TAPS Comments at 7.

needs to be accounted for, the Commission should consider that: (1) Generator owners do not and cannot play an active role in UFLS program decisions; (2) generator owners do not determine the set points for their generation; and (3) the NERC process should not be used to influence market decisions and competitiveness.

56. SWPA states that the design assessment in Requirement R4 of Reliability Standard PRC–006–1 addresses the modeling of generators having trip settings prior to the UFLS set points but that the Reliability Standard does not address how planning coordinators would resolve the need for supplemental UFLS. SWPA maintains that PRC–006–1 should include a requirement for planning coordinators to identify the UFLS entity that needs to provide supplemental UFLS, the basis for the identification, and coordination of this information with those entities and affected generator owners.

57. NYISO states that it conducts an annual survey of all generator owners within the New York Control Area for their UFLS trip setting and addresses those that have settings outside the UFLS program range established by the Northeast Power Coordinating Council (NPCC). NYISO states that it conducts a UFLS simulation that excludes non-conforming generation and a separate simulation that incorporates 260 MW of compensatory load shedding with tripping of non-conforming generation.

Commission Determination

58. Based on the comments, the Commission is persuaded to take no action to require compensation for generation losses outside of the UFLS set points (i.e., generators having trip settings prior to the UFLS underfrequency set points). Reliability Standard PRC–006–1 is an improvement because it requires planning coordinators to consider generators that trip outside of the UFLS set points when modeling and designing UFLS programs. We are persuaded by NERC's comments that it is appropriate for planning coordinators to consider generators that trip outside of the UFLS set points when designing UFLS programs, but it is inappropriate for planning coordinators to determine whether mitigation is necessary and who will be responsible for providing mitigation. For these reasons, we take no action to modify the Reliability Standard.

E. UFLS Program Coordination With Other Protection Systems

59. In the NOPR, the Commission stated that an integrated approach to the coordination of all types of protection systems (e.g., UFLS, undervoltage load shedding [37]), internally and externally to an entity's area, is required to be responsive to the 2003 Blackout Report.[38] The Commission noted that, while Reliability Standard PRC–006–1 requires coordination of UFLS programs among planning coordinators in Requirements R5, R7, and R13, it does not appear to capture the same level of coordination with other protection systems as in Requirement R1.2.8 of PRC–006–0, which was approved by the NERC Board of Trustees but left pending in Order No. 693.[39] The Commission sought comments on whether and how coordination with other protection systems is or is not achieved under the new requirements.

Comments

60. NERC states that Requirement R1.2.8 of PRC–006–0 includes a broad mandate and that the intent was to replace it with more specific requirements that are clear and measurable. NERC contends that Requirements R3, R4, and R10 of Reliability Standard PRC–006–1 include requirements for the coordination of UFLS programs with specific protections that ''are part of or could impact the UFLS program.'' [40] EEI and G&T Cooperatives likewise believe that Requirement R1.2.8 is vague, while PRC–006–1 contains the specificity to ensure that UFLS programs are adequately designed and coordinated. G&T Cooperatives maintains that coordination of UFLS and UVLS programs is already provided for in PRC–010–0, Requirement R1.1.1.

61. FRCC states that there is seldom a need to coordinate UFLS with UVLS and that the Reliability Standard PRC–006–1 correctly identifies the protection systems that entities should coordinate with UFLS programs. FRCC contends that the potential for interaction between UFLS and UVLS programs is minimal given that UVLS schemes are not deployed throughout an interconnection and are, instead, deployed in specific locations that may be exposed to low voltage for a specific contingency. NYISO likewise states that, due to the distributed nature of UFLS, there should not be any significant interaction between fault clearing protections and UFLS and that under-voltage inhibition of relays is not expected to interfere with UFLS programs.

Commission Determination

62. With regard to our concern raised in the NOPR regarding the coordination of UFLS with other protection systems, we are persuaded by NERC's comments that Reliability Standard PRC–006–1 provides an adequate level of coordination between the UFLS program and specific protection systems and controls that NERC identifies as part of, or could impact, the UFLS program.[41]

63. We are persuaded by NERC comments that ''Requirements R3, R4, and R10 of PRC–006–1 address coordination of the UFLS program with other protection and control systems * * * includ[ing] generator protections that could respond to frequency and voltage excursions, automatic Load restoration, and equipment switching that may be included in the UFLS program to control voltage.'' [42] Specifically, planning coordinators are to coordinate expected generation performance during underfrequency events and generator trip settings under PRC–006–1, Requirements R3 and R4.[43] To satisfy PRC–006–1, Requirement R10, transmission owners must provide the necessary automatic switching of elements as directed by the planning coordinator in the UFLS program and schedule.[44] To maintain the required system restoration capability required by PRC–006–1, Requirement R10, transmission owners must coordinate other protection system components with the established UFLS program components.

64. Additionally, the Commission notes that currently-effective Reliability Standard PRC–001–1 (System Protection Coordination) ensures system protection coordination for protection systems.[45] The Commission believes that this level

[37] Undervoltage load shedding (UVLS) is automatic load-shedding that sheds load to prevent local area voltage collapse. *See U.S.-Canada Power System Outage Task Force, Final Report on the August 14, 2003 Blackout in the United States and Canada: Causes and Recommendations,* at 92 (Apr. 2004) (Blackout Report), available at *http://www.ferc.gov/industries/electric/indus-act/reliability/blackout.asp.*

[38] Blackout Report at 159.

[39] Order No. 693, FERC Stats. & Regs. ¶ 31,242 at PP 1477, 1479.

[40] NERC Comments at 9.

[41] It may be appropriate to address an integrated approach to the coordination of all protections systems, as recommended by the Blackout Report, but that issue is outside the scope of this proceeding addressing Reliability Standard PRC–006–1.

[42] NERC Comments at 9.

[43] *Id.* at 9–10.

[44] *Id.* at 11.

[45] Reliability Standard PRC–001–1, Requirements R1 and R3.

of coordination between UFLS programs and other specific protection systems is adequate.

F. Identification of Island Boundaries

65. Requirement R1 of Reliability Standard PRC–006–1 directs planning coordinators to develop criteria to select areas that may form islands based on historical events and system studies. Historical events and system studies provide planning coordinators with the data necessary to determine where islands will occur based on the physics of the system. Requirement R2.3 of PRC–006–1 allows planning coordinators to ''adjust the island boundaries to differ from the Regional Entity area boundaries by mutual consent where necessary'' to preserve contiguous island boundaries that better reflect simulations.

66. In the NOPR, the Commission agreed with the premise behind Requirement R1, which requires identifying island boundaries based on where they are likely to occur as opposed to following rigid Regional Entity area boundaries, because it should result in more effective UFLS programs. The NOPR also noted that NERC, in its petition, stated that Reliability Standard PRC–006–1 allows planning coordinators to ''select islands including interconnected portions of the bulk electric system in adjacent Planning Coordinator areas and Regional Entity areas, without the need for coordinating this selection with Planning Coordinators in neighboring regions.'' [46] The Commission observed, however, that Requirement R2.3 of PRC–006–1 requires ''mutual consent'' to adjust island boundaries from Regional Entity boundaries. The Commission sought clarification concerning the required degree of cooperation and/or ''mutual consent'' between planning coordinators under the proposed Reliability Standard.

Comments

67. In its comments, NERC clarifies that ''mutual consent'' is required by part 2.3 of Requirement R2 of Reliability Standard PRC–006–1 when planning coordinators select island boundaries that do not coincide with the Regional Entity area or Interconnection boundary. NERC explains that, when a planning coordinator selects an island boundary that does not coincide with the Regional Entity area or Interconnection boundary, mutual consent must be obtained from neighboring planning coordinators to ensure that the deviation does not result in a portion of the bulk electric system being excluded from a UFLS assessment.

68. EEI states that the Reliability Standard PRC–006–1 requires ''mutual consent'' between affected planning coordinators and that the level of consent is voluntary and undefined to allow the parties to determine the level of cooperation necessary. EEI maintains that this scheme is necessary to ensure that all parts of the bulk electric system are covered within a UFLS plan.

69. MISO states that planning coordinators should be able to study islands as they see fit and without the consent of neighboring planning coordinators, which includes studying islands that deviate from Regional Entity boundaries. MISO maintains that there is no detrimental effect associated with multiple or non-coordinated island studies.

70. NYISO comments that it regularly conducts stability evaluations on a New York Control Area and regional basis and is aware of the potential breakpoints on the system.

71. EPSA states that UFLS programs are best developed on an interconnection-wide basis, not on a regional basis. EPSA notes that region-specific Reliability Standards could undermine Reliability Standards PRC–006–1 and EOP–003–2 if they do not address interregional coordination among planning coordinators.

72. PSEG states that it has concerns with the active draft regional versions of PRC–006–1 pertaining to Reliability*First* Corporation and NPCC. PSEG maintains that these regional versions will hamper needed interregional coordination for UFLS program design in the Eastern Interconnection (i.e., the proposed regional standards do not require interregional coordination among planning coordinators and may require planning coordinators who span multiple regions to follow different standards); they violate a key NERC market principle by requiring existing generator owners to procure offsetting UFLS for the early tripping of their generating units if these units cannot meet specific performance requirements; and they may contravene the Energy Policy Act of 2005 [47] by placing NERC and the regions in the role of imposing generation adequacy requirements. PSEG maintains that UFLS is an interconnection-wide issue and should be addressed on an interconnection-wide basis.

Commission Determination

73. The Commission accepts NERC's clarification of the level of consent required between planning coordinators to adjust island boundaries under Reliability Standard PRC–006–1, Requirement R2.3. As stated in the NOPR, we believe that the reliability of the bulk electric system benefits from entities basing their studies on physical characteristics, as allowed in PRC–006–1, as opposed to hewing to artificial boundaries.[48] To the extent MISO suggests in its comments that planning coordinators should not have to reach a consensus with neighboring planning authorities when adjusting island boundaries, we disagree. As NERC and EEI explain in their comments, it is important to coordinate adjustments in island boundaries to ensure that no part of the bulk electric system is inadvertently left unstudied.[49] However, nothing in PRC–006–1 precludes entities from conducting additional assessments based on any island boundaries they wish to analyze.

74. With respect to the comments from EPSA and PSEG, there are no Regional Reliability Standards currently before us in this matter and, therefore, the matter is not ripe for us to address.

G. Automatic Load Shedding and Manual Load Shedding

75. In the NOPR, the Commission observed that there are no requirements in Reliability Standard PRC–006–1 to coordinate automatic load shedding by UFLS and manual load shedding under Reliability Standard EOP–003–2. The Commission noted that once load is disconnected from the system, either automatically or manually, it cannot be used again to arrest frequency decline. The Commission expressed concern that in the event that a load resource is double-counted and removed during automatic UFLS, the manual load shedding cannot be completed if called upon. Accordingly, the Commission stated that resources allocated to each type of load shedding (i.e., automatic and manual) should not overlap. The Commission sought comments on how the coordination of automatic and manual load shedding is considered in light of the fact that the Reliability Standards do not explicitly require coordination.

Comments

76. NERC acknowledges that the Reliability Standards do not explicitly require coordination of manual load shedding and UFLS but states that

[46] NERC Petition at 75–76.

[47] Energy Policy Act of 2005, Public Law 109–58, 119 Stat. 594 (2005).

[48] NOPR, FERC Stats & Regs. ¶ 32,682 at P 46.

[49] NERC Comments at 12; EEI Comments at 10.

Reliability Standard EOP–003–2 addresses the concern that a load resource could be unintentionally double-counted. Specifically, NERC maintains that Requirement R6 of EOP–003–2 requires transmission operators and balancing authorities to include load in the manual load shedding program that is not included in the UFLS program to achieve the reliability objective of EOP–003–2.[50]

77. Wisconsin Electric and FRCC state that it is difficult for a UFLS program not to overlap with manual loadshed plans. Wisconsin Electric comments that it is ''overly conservative to prevent a load from being used in both a UFLS program and a manual loadshed plan.'' [51] Wisconsin Electric also observes that a reliability coordinator may require an entity to manually shed load that is part of a UFLS program, which the entity cannot ignore. FRCC maintains that a non-overlap rule is likely to have a negative impact on reliability because it may reduce the amount of load available to address capacity emergencies. FRCC further contends that underfrequency events are rare and it is even less likely for an underfrequency event to coincide with a capacity emergency.

78. Dominion states that the Commission should not force coordination of manual load shedding and UFLS load shedding because it would prevent balancing authorities and transmission operators from using currently available tools to manage emergency conditions. Dominion contrasts the precision of manual load shedding with the widespread automatic response provided by UFLS programs. According to Dominion, forced coordination could remove manual load shedding from the emergency response toolkit for local issues, which, according to Dominion, could allow them to turn into cascading events. EEI states that the purpose of UFLS programs and manual load shedding are separate. EEI argues that, while a broad understanding of the operation of each program is important, coordination to the level implied by the NOPR serves no purpose since each program addresses different problems. EEI further notes that coordination in the form of ''information sharing'' already occurs. NYISO also states that manual load shedding and UFLS address different issues and should be addressed in separate Reliability Standards.

79. SWPA states that there is a need to address what consideration planning authorities give to other protective schemes and remedial action plans. SWPA maintains that Reliability Standard PRC–006–1 should address how a balancing authority and transmission operator address overlap concerns where most of its balancing authority area entities are subject to load shedding plans under Reliability Standard EOP–003–2 but these loads are also subject to UFLS plans under PRC–006–1.

Commission Determination

80. Based on the comments, we find that there is an adequate level of coordination between UFLS and manual load shedding. We are persuaded by NERC's comments that the term ''additional load'' in Reliability Standard EOP–003–2, Requirement R6, includes resources allocated to manual load shedding that are not included in the UFLS program. UFLS and manual load shedding programs are developed separately and have, as EEI stated, separate purposes. As such, to avoid insufficiencies in available load if manual load shedding is needed after UFLS has been activated, UFLS and manual load shedding programs cannot be planned to shed the same load.

H. Elimination of Requirements for Balancing Authorities in EOP–003–2

81. In the NOPR, the Commission observed that Requirements R2, R4, and R7 of the currently-effective Reliability Standard EOP–003–1 apply to transmission operators and balancing authorities but that Reliability Standard EOP–003–2 eliminates balancing authorities from Requirements R2, R4, and R7. The Commission sought clarification as to why these balancing authority responsibilities were not incorporated into Reliability Standards PRC–006–1 or EOP–003–2. The Commission also sought comments as to why balancing authorities should not be informed of UFLS program plans that directly impact balancing authority functions.

Comments

82. NERC states that Reliability Standard EOP–003–2 removes requirements on UFLS design, incorporates them in Reliability Standard PRC–006–1, and assigns those activities to planning coordinators. NERC further states that EOP–003–2 does not remove any requirements for UVLS, which are assigned to transmission operators. NERC maintains that, while balancing authorities contribute to managing Interconnection frequency by balancing load and generation resources in real-time, UFLS and UVLS programs are automatic and must be set in advance. NERC, however, agrees that balancing authorities should be informed of UFLS program plans that directly impact the balancing authority function.

83. EEI, TAPS, MISO, Dominion and NYISO largely support NERC's comments. EEI states that the changes in Reliability Standard EOP–003–2 are consistent with the roles and responsibilities of balancing authorities and transmission operators. EEI also maintains that balancing authorities are already informed of UFLS programs by transmission operators because balancing authorities and transmission operators ''are specifically identified as coordinating other load shedding plans as identified in EOP–003–2'' and to ''effectively develop those plans [balancing authorities] and [transmission operators] must have knowledge of the UFLS programs of which [transmission operators] are intimately aware through PRC–006–1.'' [52]

84. TAPS states that Reliability Standards PRC–006–1 and EOP–003–2 clarify the requirements in the existing Reliability Standards and assign them to the functional entities best suited to program design. TAPS also states that Reliability Standard PRC–001–1, Requirement R1 ensures that balancing authorities are familiar with UFLS programs because the requirement provides that they ''shall be familiar with the purpose and limitations of protection system schemes applied in its area.'' [53]

85. MISO states that balancing authorities need not be informed of UFLS programs because planning coordinators are the functional entities tasked with overseeing those programs. MISO also contends that requiring planning coordinators to report to balancing authorities on UFLS programs would impose additional costs with little benefit to reliability. MISO notes, however, that balancing authorities could benefit if NERC periodically published prevailing UFLS set points by planning coordinator area.

86. Dominion states that planning coordinators should not be required to inform balancing authorities of UFLS program plans because balancing authorities have no role in the design and implementation of UFLS and have no action to take to affect the successful operation of UFLS.

87. NYISO comments that balancing authorities have no role in load shedding and agrees with the removal of

[50] NERC Comments at 12.

[51] Wisconsin Electric Comments at 3.

[52] EEI Comments at 13.

[53] TAPS Comments at 8–9.

UFLS references from Reliability Standard EOP–003–2.

88. SWPA states that balancing authorities, by definition, do not perform the functions referred to in Reliability Standards PRC–006–1 or EOP–003–2, Requirements R2, R4, and R7. However, SWPA believes that PRC–006–1 should incorporate language that ensures that balancing authorities are kept informed of UFLS program plans that directly impact the balancing authority functions.

Commission Determination

89. The Commission accepts the elimination of requirements for balancing authorities in Reliability Standard EOP–003–2. NERC states in its comments that ''all activities required for UFLS programs in the existing standards are incorporated into PRC–006–1, and are assigned to the Planning Coordinator,'' [54] and that balancing authorities will still be made aware of UFLS programs in order to ''be familiar with the purpose and limitations of protection system schemes applied in its area,'' [55] as stated in Reliability Standard PRC–001–1, Requirement R1. To that end, the Commission believes that the comments address the questions raised in the NOPR regarding the elimination of balancing authority responsibility for Requirements R2, R4, and R7 of EOP–003–2.

I. Violation Risk Factors and Violation Severity Levels

90. In the NOPR, the Commission proposed to approve the VRFs and VSLs in Reliability Standards PRC–006–1 and EOP–003–2. However, the Commission sought comments on one VSL and one VRF for PRC–006–1.

91. The Commission stated that the ''Lower VSL'' assignment for Requirement R8 in PRC–006–1 applies when a UFLS entity fails to provide data to its planning coordinator for 5 to 10 calendar days following the schedule specified by the planning coordinator. The Commission noted in the NOPR that Requirement R8 of PRC–006–1 does not include a 5-day grace period for providing data to planning coordinators and thus the subject VSL assignment may be inconsistent with the Commission's VSL Guideline 3.

92. The Commission noted that NERC proposed a ''Medium'' VRF for Reliability Standard PRC–006–1, Requirement R5, which requires planning coordinators to coordinate their UFLS program design with other planning coordinators whose area is in part of the same identified island. The Commission observed the statement in NERC's petition that Requirement R5 is ''not related to similar reliability goals in other standards.'' [56] However, the Commission explained that coordination of load shedding plans is required in a similar manner in Requirement R3 of currently-effective Reliability Standard EOP–003–1, which includes a VRF of ''High.'' [57] The Commission stated that the lack of coordination of UFLS programs among planning coordinators within the same identified island could lead to ineffective UFLS operations and further cascading outages within the island when UFLS is activated. The Commission explained that this might be inconsistent with Guideline 3 of the Commission's VRF Guidelines states that ''[a]bsent justification to the contrary, the Commission expects the assignment of Violation Risk Factors corresponding to Requirements that address similar reliability goals in different Reliability Standards would be treated comparably.'' [58]

Comments

93. NERC agrees with the NOPR regarding both the ''Lower VSL'' for Requirement R8 of Reliability Standard PRC–006–1 and the VRF for Requirement R5 of PRC–006–1. In its comments, NERC proposes to modify the ''Lower VSL'' to remove the phrase ''more than 5 calendar days but'' to address the concern stated in the NOPR. NERC also proposes to modify the VRF for Requirement R5 by raising it from ''Medium'' to ''High.''

94. EEI, SWPA, and NYISO agree with the need to modify the VSL for Requirement R8 of PRC–006–1, consistent with NERC's proposal. NYISO also supports changing the VRF for PRC–006–1, Requirement R5.

Commission Determination

95. Consistent with the proposal in NERC's comments, the Commission directs the ERO to modify the language of the Lower VSL for Reliability Standard PRC–006–1, Requirement R8 and the Medium VRF for PRC–006–1, Requirement R5. NERC is directed to submit the revised VRF and VSL within 30 days of the effective date of this final rule.

J. Implementation Plan and Effective Date

96. In the NOPR, the Commission noted that NERC requests an effective date for Reliability Standards PRC–006–1 and EOP–003–2 of one year following the first day of the first calendar quarter after applicable regulatory approvals with respect to all Requirements of the proposed Reliability Standards *except* Parts 4.1 through 4.6 of Requirement R4 of PRC–006–1. With respect to Parts 4.1 through 4.6 of Requirement R4 of PRC–006–1, NERC requests an effective date of one year following the receipt of generation data as required in Reliability Standard PRC–024–1,[59] but no sooner than one year following the first day of the first calendar quarter after applicable regulatory approvals of PRC–006–1. The Commission sought comments about any potential reliability gaps that may occur during the development and implementation of PRC–024–1, such as how the planning coordinators will adequately determine and apply UFLS simulations and plans in the absence of generator trip settings.

Comments

97. NERC maintains that there should not be a reliability gap because planning coordinators have access to and utilize trip settings in UFLS assessments. NERC explains its proposal by noting that generator owners currently cannot be compelled to provide trip settings to planning coordinators. NERC states that the implementation schedule defers a compliance obligation for planning coordinators to model the trip settings until a compliance obligation for generator owners to provide these settings exists.

98. EEI believes that a reliability gap will exist until draft Reliability Standard PRC–024–1 is approved, but it believes that the gap is minor and manageable. EEI agrees with NERC that information that will be mandated in PRC–024–1 is already supplied through mutual cooperation between entities. EEI states that the Commission might consider directing NERC to reevaluate its priority list to determine if the PRC–024–1 project is being given sufficient priority.

99. TAPS comments that planning coordinators have the ability to run UFLS simulations, even though modeling generator trip settings is not currently mandatory, because all

[54] NERC Comments at 13.

[55] NERC Comments at 14.

[56] NERC Petition at 46.

[57] Reliability Standard EOP–003–2 includes the same VRF assignment of ''High'' for Requirement R3.

[58] *North American Electric Reliability Corp.,* 119 FERC ¶ 61,145, at P 25 (2007).

[59] Draft Reliability Standard PRC–024–1 addresses ''Generator Performance During Frequency and Voltage Excursions'' and is currently being developed in the NERC standard drafting process under Project 2007–09 (Generator Verification), which is one of NERC's priority projects.

significantly sized generators are included in models. TAPS contends that while some generators that trip outside of the UFLS set points may not be modeled, this will not have a significant impact on the reliability of the bulk electric system.

Commission Determination

100. The Commission approves the implementation plan and effective dates of Reliability Standards PRC–006–1 and EOP–003–2. We agree with EEI that there is a reliability gap given the lack of mandatory requirements for providing generator trip settings, which will continue until draft Reliability Standard PRC–024–1 is approved. The Commission, however, also agrees with EEI that the gap is limited because the information mandated by PRC–024–1 is already supplied through mutual cooperation between utilities. To ensure that any gap pending implementation of PRC–024–1 remains limited, the Commission encourages the current practice of voluntarily sharing generator trip settings between entities to continue.

III. Information Collection Statement

101. The Office of Management and Budget (OMB) regulations require that OMB approve certain reporting and recordkeeping (collections of information) imposed by an agency.[60] Upon approval of a collection(s) of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

102. The Commission is submitting these reporting and recordkeeping requirements to OMB for its review and approval under section 3507(d) of Paperwork Reduction Act of 1995.[61] The Commission solicited comments on the need for and the purpose of the information contained in Reliability Standard PRC–006–1 and EOP–003–2 and the corresponding burden to implement them. The Commission received comments on specific requirements in the Reliability Standards, which we address in this final rule. However, we did not receive any comments on our reporting burden estimates.

103. This final rule approves Reliability Standards PRC–006–1 and EOP–003–2, which would replace currently effective Reliability Standards PRC–007–0, PRC–009–0, EOP–003–1 and NERC-approved Reliability Standard PRC–006–0.[62] As noted previously, Reliability Standard PRC–006–0 was never approved by the Commission, and therefore has never been mandatory and enforceable. On the other hand, Reliability Standards PRC–007–0 and PRC–009–0 were approved by the Commission and are currently mandatory and enforceable. Because Proposed Reliability Standard PRC–006–1 incorporates the requirements from Reliability Standards PRC–006–0, PRC–007–0, and PRC–009–0 some of the existing requirements will become mandatory and enforceable (where previously they were voluntary), while others continue to be so. To properly account for the burden on respondents, the Commission will treat the burden resulting from NERC-approved Reliability Standard PRC–006–0 as essentially new to the industry, even though it is likely that most applicable entities have already been complying.[63]

104. The reporting requirements in Reliability Standard EOP–003–2 are virtually the same as those in currently effective Reliability Standard EOP–003–1. The difference is that Reliability Standard EOP–003–2 eliminates balancing authorities from Requirements R2 and from Measure M1.[64] This requirement and measure deal with establishing and documenting automatic load shedding plans.

105. *Public Reporting Burden:* Our estimate below regarding the number of respondents is based on the NERC compliance registry as of July 29, 2011. According to the NERC compliance registry, there are 72 planning coordinators and 126 balancing authorities. The individual burden estimates are based on the time needed to gather data, run studies, and analyze study results to design or update the UFLS programs. Additionally, documentation and the review of UFLS program results by supervisors and management is included in the administrative estimations. These are consistent with estimates for similar tasks in other Commission approved standards.

PRC–006–1 (automatic underfrequency load shedding)[65]	Number of respondents annually	Number of responses per respondent	Average burden hours per response		Total annual burden hours
	(1)	(2)	(3)		(1) × (2) × (3)
PCs*: Design and document Automatic UFLS Program	72	1		120	8,640
PCs: Management Review of Documentation	72	1		40	2,880
PCs: Record Retention	72	1		16	1,152
Total					12,672
EOP–003–2 (Load Shedding Plans)[66]					
Removal of BAs* from Reporting Requirements in R2 and M1 (Burden Reduction).	126	1	Reporting	−10	−1,260
	126	1	Record Retention	−1	−126
Total					−1,386
Net Change in Burden *(Total Annual Hours for Collection)*					11,286

[60] 5 CFR 1320.11.

[61] 44 U.S.C. 3507(d)

[62] PRC–006–0 was not approved by the Commission but remained effective as a NERC-approved standard (but not mandatory or enforceable). The other three standards were approved by the Commission. *Mandatory Reliability Standards for the Bulk-Power System,* Order No. 693, FERC Stats. & Regs. ¶ 31,242, *order on reh'g,* Order No. 693–A, 120 FERC ¶ 61,053 (2007).

[63] This statement is made because currently effective Reliability Standards PRC–007–0 and PRC–009–0 required UFLS entities to follow the UFLS program implemented by Reliability Standard PRC–006–0. Therefore, it is likely that entities have already been following the requirements contained in Reliability Standard PRC–006–0.

[64] Balancing authorities are also removed from Requirements R4 and R7, but these do not have reporting requirements associated with them.

[65] Reliability Standard PRC–006–1 applies to both planning coordinators and to UFLS entities. However, the burden associated with the UFLS entities is not new because it was accounted for under Commission approved Reliability Standards PRC–007–0 and PRC–009–0.

[66] Transmission operators also have to comply with Reliability Standard EOP–003–2. Since the applicable reporting requirements (and associated burden) have not changed from the existing standard, these entities are not included here.

*PC = Planning Coordinator; BA = Balancing Authority.

Total Net Annual Cost (Reporting + Record Retention)[67]: = $1,414,656 − $154,728 = $1,259,928.

- *Total Reporting Cost for Planning Coordinators:* = 11,520 hours @ $120/hour = $1,382,400.
- *Total Record Retention Cost for Planning Coordinators:* 1,152 hours @ $28/hour = $32,256.
- Total Reporting and Record Retention Cost Savings for Balancing Authorities: = (1,260 hours @ $120/hour) + (126 hours @ $28/hour) = $154,728.

Title: Mandatory Reliability Standards for the Bulk-Power System

Action: Proposed Collection FERC–725A.

OMB Control No.: 1902–0244.

Respondents: Businesses or other for-profit institutions; not-for-profit institutions.

Frequency of Responses: On Occasion.

Necessity of the Information: This Final Rule approves the requested modifications to Reliability Standards pertaining to automatic underfrequency load shedding. The Reliability Standards help ensure the reliable operation of the bulk electric system by arresting declining frequency and assisting recovery of frequency following system events leading to frequency degradation.

Internal Review: The Commission has reviewed the Reliability Standards and made a determination that its action is necessary to implement section 215 of the FPA. These requirements, if accepted, should conform to the Commission's expectation for UFLS programs as well as procedures within the energy industry.

106. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov*, phone: (202) 502–8663, fax: (202) 273–0873].

107. For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the Commission and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–4638, fax: (202) 395–7285]. For security reasons, comments to OMB should be submitted by email to: *oira_submission@omb.eop.gov.* Comments submitted to OMB should include Docket Number RM11–20 and OMB Control Number 1902–0244.

IV. Environmental Analysis

108. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[68] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[69] The actions proposed here fall within this categorical exclusion in the Commission's regulations.

V. Regulatory Flexibility Act

109. The Regulatory Flexibility Act of 1980 (RFA)[70] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule and that minimize any significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[71] The SBA has established a size standard for electric utilities, stating that a firm is small if, including its affiliates, it is primarily engaged in the transmission, generation and/or distribution of electric energy for sale and its total electric output for the preceding twelve months did not exceed four million megawatt hours.[72]

110. Reliability Standard PRC–006–1 establishes design, assessment, and documentation requirements for automatic UFLS programs. It will be applicable to planning coordinators and entities that are responsible for the ownership, operation, or control of UFLS equipment. Reliability Standard EOP–003–2 removes balancing authorities from having to comply with Requirement R2 and Measure M1 of the standard. Comparison of the NERC compliance registry with data submitted to the Energy Information Administration on Form EIA–861 indicates that perhaps as many as 8 small entities are registered as planning coordinators and 18 small entities are registered as balancing authorities. The Commission estimates that the small planning coordinators to whom the Reliability Standard will apply will incur compliance and recordkeeping costs of $157,184 ($19,648 per planning coordinator) associated with the Standard's requirements. The small balancing authorities will receive a savings of $154,728 ($8,596 per balancing authority). Accordingly, Reliability Standards PRC–006–1 and EOP–003–2 should not impose a significant operating cost increase or decrease on the affected small entities.

111. Based on this understanding, the Commission certifies that these Reliability Standards will not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis is required.

VI. Document Availability

112. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington DC 20426.

113. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

[67] The hourly reporting cost is based on the cost of an engineer to implement the requirements of the rule. The record retention cost comes from Commission staff research on record retention requirements.

[68] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

[69] 18 CFR 380.4(a)(2)(ii).

[70] 5 U.S.C. 601–612.

[71] 13 CFR 121.101.

[72] 13 CFR 121.201, Sector 22, Utilities & n.1.

114. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov*, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

115. These regulations are effective July 10, 2012. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 18 CFR Part 40

Electric power; Electric utilities; Reporting and record keeping requirements.

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

Appendix

Commenters

Abbreviation	Commenter
Dominion	Dominion Resources Services, Inc.
EEI	Edison Electric Institute.
EPSA	Electric Power Supply Association.
FRCC	Florida Reliability Coordinating Council, Inc.
G&T Cooperatives	Associated Electric Cooperative, Inc.; Basin Electric Power Cooperative; and Tri-State Generation and Transmission Association, Inc.
KCP&L	Kansas City Power & Light Company and KCP&L Greater Missouri Operations Company.
MISO	Midwest Independent Transmission System Operator, Inc.
NERC	North American Electric Reliability Corporation.
NYISO	New York Independent System Operator, Inc.
PSEG	Public Service Electric and Gas Company; PSEG Power LLC; PSEG Energy Resources & Trade LLC.
SWPA	Southwestern Power Administration.
TAPS	Transmission Access Policy Study Group.
Wisconsin Electric	Wisconsin Electric Power Company.

[FR Doc. 2012–11316 Filed 5–10–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA–1999–F–0021; formerly 1999F–2673]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; denial of requests for a hearing and response to objections.

SUMMARY: The Food and Drug Administration (FDA) is denying requests for a hearing on the final rule that amended the food additive regulations to provide for the safe use of ionizing radiation for the control of microbial pathogens in seeds for sprouting. After reviewing objections to the final rule and requests for a hearing, FDA has concluded that the objections do not justify a hearing or otherwise provide a basis for revoking the regulation.

FOR FURTHER INFORMATION CONTACT: Teresa A. Croce, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1281.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of August 16, 1999 (64 FR 44530), FDA published a notice announcing the filing of a food additive petition (FAP 9M4673) submitted by Caudill Seed Co., Inc., to amend the regulations in part 179 *Irradiation in the Production, Processing, and Handling of Food* (21 CFR part 179) by providing for the safe use of ionizing radiation to control microbial pathogens in seeds for sprouting. In response to this petition, FDA issued a final rule in the **Federal Register** of October 30, 2000 (65 FR 64605), permitting the irradiation of seeds for sprouting to control microbial pathogens in alfalfa and other sprouting seeds at an absorbed dose not to exceed 8.0 kiloGray (kGy) (hereafter referred to as the ''seeds for sprouting rule''). FDA based its decision on data in the petition and in its files. The preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by November 29, 2000).

II. Objections and Requests for a Hearing

Section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(f)(1)) provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, ''specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor [sic], and requesting a public hearing upon such objections.''

Under the food additive regulations at 21 CFR 171.110, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following publication of the final rule permitting the irradiation of seeds for sprouting to control food-borne pathogens, FDA received numerous submissions within the 30-day objection

period. FDA received a letter from Public Citizen (letter to Docket No. 4602, November 15, 2000) containing eight numbered objections with a request for a hearing on each objection, and a letter by Jonathan Sprouts, Inc. (letter to Docket No. 5055, December 19, 2000), expressing concern over the labeling of sprouts grown from seeds that have been irradiated. The remaining submissions expressed general opposition to the final rule. Those submissions are brief form letters which state either one or a combination of the following general concerns: That no toxicity studies were performed directly on the consumable sprouts, that nutrition data was submitted for irradiation doses of 6 kGy and not the petitioned maximum of 8 kGy, or that the lack of labeling for sprouts grown from irradiated seeds was a concern. Those concerns were raised with more specificity by the other two submissions and will be addressed as part of the response to those submissions in section IV of this document.

III. Standards for Granting a Hearing

Specific criteria for deciding whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (e.g., if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the act or any FDA regulation; and (6) the requirements in other applicable regulations, e.g., 21 CFR 10.20, 12.21, and 12.22, and in the notice issuing the final regulation or the notice of opportunity for hearing are met.

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214 (1980), *reh. denied,* 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–21 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *U.S. EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies in administrative proceedings (see § 12.28).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held (*Pineapple Growers Association* v. *FDA,* 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the Agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960)). A hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue'' (*Pactra Industries* v. *CPSC,* 555 F.2d 677, 684 (9th Cir. 1977)). A hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County, Inc.* v. FPC, 414 F.2d 1125, 1128 (DC Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir.), *cert. denied,* 358 U.S. 872 (1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality, such as collateral estoppel, can be validly applied to the administrative process (see *Pac. Seafarers, Inc.* v. *Pac. Far East Line, Inc.,* 404 F.2d 804, 809 (DC Cir. 1968), *cert. denied,* 393 U.S. 1093 (1969)). In explaining why these principles ought to apply to an agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote: ''The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than one fair opportunity.'' *Retail Clerks Union, Local 1401* v. *NLRB,* 463 F.2d 316, 322 (DC Cir. 1972; see also *Costle* v. *Pacific Legal Foundation,* 445 U.S. at 215–217.

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

IV. Analysis of Objections and Response to Hearing Requests

The letter from Public Citizen contains eight numbered objections and requests a hearing on each of them. Where Public Citizen's objections overlap, FDA has combined its response. The letter from Jonathan Sprouts, Inc., raised one objection and requested a hearing on its objection. FDA addresses each of the objections below, as well as the evidence and information filed in support of each, comparing each objection and the information submitted in support of it to the standards for granting a hearing in § 12.24(b).

A. Application of 100-Fold Safety Factor

The first objection raised by Public Citizen in response to the seeds for sprouting rule contends that the Agency failed to apply a 100-fold safety factor, as required by § 170.22 (21 CFR 170.22),[1] for the irradiation of seeds for sprouting. While FDA agrees that § 170.22 states that FDA will use a 100-fold safety factor when applying animal data to man, FDA notes that § 170.22 provides for use of a different safety factor ''where evidence is submitted which justifies use of a different safety factor.''

The Agency has determined that use of a different safety factor is appropriate based on the considerable body of data available from studies involving irradiated foods fed to laboratory animals and reviewed by FDA. FDA's Bureau of Foods Irradiated Foods

[1] Section 170.22 states: ''In accordance with section 409(c)(5)(C) of the Act, the following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.''

Committee (BFIFC) determined that the studies involving irradiated foods that they evaluated did not appear to show adverse effects (Ref. 1). These studies, taken as a whole, serve as an independent method to assess toxicological safety. The studies included in that evaluation are those which have been relied on by the Agency in previous evaluations of the safety of other irradiated foods, such as lettuce, spinach, molluscan shellfish, shell eggs, meat, and poultry (see 73 FR 49593, August 22, 2008; 70 FR 48057, August 16, 2005; 65 FR 45280, July 21, 2000; 62 FR 64107, December 3, 1997; 55 FR 18538, May 2, 1990; and 51 FR 13376, April 18, 1986), and additional data and information from FDA files or other published reports regarding studies in which animals were fed a wide variety of foods irradiated at different doses.

The Agency's analysis incorporates the principle that toxicological data collected from studies on a given food may be applied to the toxicological evaluation of foods of a similar generic class and that data from foods irradiated at high doses can be applied to the toxicological evaluation of foods of similar generic class receiving lower doses (Ref. 2). The Agency's analysis also draws upon the integrated toxicological database derived from the extensive body of work reviewed by the Agency (see 51 FR 13376 at 13378) and by WHO [2] in previous evaluations of the safety of irradiated foods (Refs. 3 and 4).

In light of the substantial data and the toxicological assessments that have been reviewed by FDA, the Agency concludes that under § 170.22 the Agency is not required to apply the 100-fold safety factor to the use of ionizing radiation for seeds for sprouting. This collective information is sufficient to justify the use of a different safety factor. Further, the applicability of § 170.22 is a legal issue, and a hearing will not be granted on issues of law (§ 12.24(b)(1)).

[2] During the early 1980s, a joint Food and Agriculture Organization/International Atomic Energy Agency, World Health Organization (FAO/IAEA/WHO) Expert Committee evaluated the toxicological and microbiological safety and nutritional adequacy of irradiated foods. The Expert Committee concluded that irradiation of any food commodity at an average dose of up to 10 kGy presents no toxicological hazard (Ref. 3). In the 1990s, WHO reanalyzed the safety data including additional studies (see 51 FR 13376 at 13378) and concluded that the integrated toxicological database is sufficiently sensitive to evaluate safety and that no adverse toxicological effects due to irradiation were observed in the dose ranges tested (Ref. 4).

B. Application of the National Academy of Sciences-National Research Council Principles and Procedures

Public Citizen's second objection asserts that FDA did not follow the ''principles and procedures for establishing the safety of food additives stated in current publication of the National Academy of Sciences-National Research Council,'' as required by § 170.20.

The Agency has consistently taken the position that many scientifically valid types of data may properly support a finding that the proposed use of a food additive is safe. The Agency pointed out in the molluscan shellfish final rule (70 FR 48057 at 48068) that the National Academy of Sciences-National Research Council testing standards and guidelines have been stated in relatively general terms and that in practice, FDA has applied exposure and toxicological criteria that were both current for the time and appropriate for assessing the safety of a particular food additive.

In its objection, Public Citizen asserts that FDA failed to properly interpret its own regulation, but has provided no new information that would refute the Agency's reasoning. The objection implies that the Agency is obligated to explicitly discuss its consideration of National Academy of Sciences-National Research Council guidelines in its rules, but there is nothing in § 170.20 that imposes such an obligation on the Agency. Further, the applicability of § 170.20 is a legal issue, and a hearing will not be granted on issues of law (§ 12.24(b)(1)). Public Citizen has not provided a basis for a hearing and FDA is denying their request for a hearing based on this objection.

C. Toxicology Issues

Public Citizen objects to the seeds for sprouting final rule because the petitioner, Caudill Seed Co. Inc., submitted, ''[n]o conventional animal toxicity studies on sprouts from irradiated seeds.'' Additionally, Public Citizen asserts that the references contained within FAP 9M4673 ''do not address the potential toxicity of irradiated sprouts.''

The Agency agrees that the petition did not include toxicological studies conducted using irradiated sprouts. As noted in the seeds for sprouting final rule (65 FR 64605), the Agency has reviewed both the data included in its database, as well as the published references, submitted by the petitioner, of toxicology studies related to irradiated foods. FDA has consistently taken the position that various scientifically validated types of data may properly support a safety determination for a proposed use of a food additive (see § 170.20). In the case of food irradiation, the Agency has taken advantage of the extensive research and large body of knowledge, such as the information compiled by BFIFC and other studies in FDA's files, concerning the principles of radiation chemistry and the chemical composition of foods.

Public Citizen also contends that FDA's statement that the ''petitioner submitted published articles and other study reports containing data and information related to seeds for sprouting * * * in the areas of radiation chemistry [and] toxicity'' in the final rule is incorrect. Public Citizen's claim is without merit. The petitioner provided articles on the toxicity of irradiated foods along with their submission, which are listed and summarized in the toxicology memorandum (Ref. 5). As previously stated, in reviewing the petitioner's application, FDA considered the articles submitted by the petitioner in addition to relevant international reports and relevant scientific articles in FDA's files (see e.g. Refs. 2, 6, and 7). However, FDA does agree that there were no toxicological studies conducted using irradiated seeds for sprouting. FDA has consistently taken the position that it is unnecessary for a safety analysis to be performed involving the specific food to be irradiated. As noted in the meat final rule (62 FR 64107 at 64112), the Agency relies on scientific studies evaluating the extent to which safety data on an irradiated food type can be extrapolated to other food types and the extent to which individual studies of irradiated foods can be evaluated as a whole (Ref. 4). Thus, data and information derived from studies of irradiated foods in general are sufficient to support a determination of safety for irradiated seeds for sprouting. Public Citizen's suggestion that such information is not sufficient to support a determination of safety is unsupported by specific data or other factual information.

Public Citizen failed to include any new information or data that would refute the Agency's findings about the toxicity of irradiated seeds for sprouting. The request for a hearing merely alleges that there is a potential for harm, without providing any evidence that the Agency has not considered previously. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)). The objectors must, at a minimum, raise a material issue

concerning which a meaningful hearing might be held.

D. Radiolysis Products

Public Citizen alleges that there are unsubstantiated statements contained in the review memorandum and final rule regarding radiolytic byproducts. There are two parts to this objection; the Agency will address each part as follows.

The first statement to which Public Citizen objects is found in the Chemistry Memorandum from K. Morehouse to J. Ziyad dated February 23, 2000 (Ref. 8), asserting that ''radiolysis products which may have been formed by irradiation of the seeds will be 'diluted' in the final product * * *. Also, it is likely that the water-soluble products will be removed by the growth medium.'' Public Citizen claims that this statement is unfounded because no data was cited regarding the dilution potential of radiolytic byproducts.

The Agency disagrees that the statement was unsubstantiated. The full statement is as follows: ''As the seeds mature and form sprouts, radiolysis products which may have been formed by irradiation of the seeds will be ''diluted'' in the final product. For example, alfalfa seeds contain only 7.4 percent water whereas alfalfa sprouts contain 88.3 percent water (see Table I of Ref. 8). Also, it is likely that water-soluble products will be removed by the growth medium.''

''Table I,'' referred to in the previous quotation, contains the nutrient composition for alfalfa seeds and raw alfalfa sprouts. This data was obtained from a published study which determined the nutrient content of various seeds and sprouts (Ref. 9). It is apparent from the data supplied that as the seeds sprout to the final product, they absorb water, in the case of alfalfa sprouts the water content increases from 7.4 percent to 88.3 percent. It follows that any byproducts would be diluted by the absorption of water, which is the growth medium for sprouts. The same study asserts that it is possible for sugars to leach into the growth medium during the sprouting procedure; therefore, it is likely that other water-soluble products could also be removed by the growth medium. Furthermore, Public Citizen did not provide any information related to the safety of irradiated seeds for sprouting that the Agency had not considered, and the objection contains no information that would cause the Agency to change its safety determination. An objector must make an adequate proffer of evidence to support its allegations and to show that they provide a basis on which to call into question the Agencies conclusions (§ 12.24(b)(2)). Public Citizen has not provided a basis for a hearing, and FDA is denying Public Citizen's request for a hearing based on this objection.

Public Citizen also objects to the Agency's conclusion that because the concentrations and types of radiolysis products formed by the irradiation of seeds for sprouting will be comparable to those products produced by the irradiation of foods of similar composition the chemical compositions of sprouts grown from irradiated seeds will not differ in any significant manner from sprouts grown from seeds that have not been irradiated. Public Citizen feels that these statements are unsupported and is requesting a hearing based on this matter.

FDA disagrees with the allegation that the statements made in the final seed for sprouting rule (65 FR 64605) are unsupported. Through information compiled by FDA and the materials submitted with each food additive petition involving irradiation (see e.g., section IV.A of this document), FDA has established that the effect ionizing radiation has on the characteristics of foods are a direct result of the chemical reactions induced by the absorbed radiation. This large body of data includes studies regarding the effects of ionizing radiation on different foods under various conditions of irradiation allowing FDA to extrapolate data obtained from one food to other foods (for more information see 73 FR 49593 at 49594 and 70 FR 48057 at 48059). Research has established that the types and amounts of products generated depend on the chemical constituents of the food and the conditions of radiation (Refs. 6, 7, and10). See the final rule permitting the irradiation of meat (62 FR 64107) for a more in depth discussion of radiation chemistry, nutrition, toxicology, and microbiology related to irradiation of foods under various conditions of use. Additionally, the review memorandum and the evidence reviewed and discussed therein, support the statement that radiolytic byproducts would be formed in low amounts in seeds for sprouting (Ref. 8). The Agency also notes that ionizing radiation causes fewer chemical changes in dry material (i.e. the seeds for sprouting) than in fresh fruits and vegetables due to the increased water content of the fresh items (Ref. 6).

Public Citizen's assertion provides no basis to challenge FDA's assessment of the safety of irradiated seeds for sprouting. A hearing will not be granted on the basis of mere allegations or general descriptions of positions and contentions (§ 12.24(b)(2)). The objector must, at a minimum, raise a material issue concerning which a meaningful hearing might be held. Public Citizen has not provided a basis for a hearing; therefore, FDA is denying their request for a hearing based on this objection.

E. Nutritional Considerations

In its request for a hearing, Public Citizen questions the nutritional adequacy of the irradiated seeds for sprouting and cites an FDA toxicology review memorandum (Ref. 5) in which the reviewer describes the data submitted by the petitioner as ''crude'' and notes a discrepancy between laboratory assessments in the vitamin A content of sprouts grown from irradiated seeds. Moreover, Public Citizen objects to the final rule on the grounds that nutritional assessments were conducted on sprouts grown from seeds that were irradiated at 6 kGy, rather than the petitioned maximum of 8 kGy.

As noted in the final rule, there were no relevant losses in the vitamin A content when comparing the sprouts grown from irradiated seeds to the control sprouts, which were grown from non-irradiated seeds. Rather, the vitamin A content was higher in all instances comparing the sprouts grown from irradiated seeds to the control seeds (65 FR 64605). The final rule also indicated that any vitamin loss that occurs in sprouts grown from irradiated seeds is expected to be inconsequential when compared to the total dietary nutrient consumption (Ref. 5).

In response to Public Citizen's objection based on the studies conducted at 6 kGy as opposed to 8 kGy, the Agency notes that there were no nutritional losses associated with sprouts grown from seeds irradiated at 6 kGy. Changes in the level of vitamins associated with irradiation are gradual with each increasing dose; scientific evidence does not support a threshold effect above which significant losses would occur (Ref. 6). Therefore, it is reasonable to anticipate that sprouts grown from seeds irradiated at 8 kGy would not lead to nutritionally relevant losses either. Furthermore, the Codex Alimentarius Commission (Codex) published its standard for irradiated foods in 1983 for adoption by Codex member countries (Ref. 11). This standard was based on the conclusion that the irradiation of any food commodity at an overall average dose of up to 10 kGy presents no concerns (Ref. 3). The Codex standard was revised in

2003,[3] at which time Codex integrated the joint FAO/IAEA/WHO study group conclusion that food irradiated to any dose appropriate to achieve the intended technological effect is both safe to consume and nutritionally adequate (i.e. at doses up to and above 10 kGy) (Ref. 12).

Overall, Public Citizen's request for a hearing suggests that there is potential for harm from possible nutritional losses from the irradiation of seeds for sprouting, without providing any evidence to support this suggestion. An objector must make an adequate proffer of evidence to support its allegations and to show that they provide a basis on which to call into question the Agency's conclusions. A hearing will be denied if the Commissioner of Food and Drugs concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate (§ 12.24(b)(3)). Public Citizen does not submit or otherwise identify any factual data that would cause the Agency to alter its conclusions about the nutritional changes in irradiated seeds. Therefore, FDA is denying the request for a hearing based on this objection.

F. Labeling Concerns

The final objection to the seeds for sprouting rule was submitted by Jonathan Sprouts, Inc, objecting to the lack of a requirement that sprouts grown from seeds that have been irradiated be labeled as treated by irradiation. Some of the general objections FDA received to the seeds for sprouting final rule also raised this point. Most of these objections were brief and expressed general dissatisfaction regarding FDA's decision on labeling, but did not provide any substantive data or information. Jonathan Sprouts, Inc., claimed that there are morphological differences between sprouts grown from irradiated versus non-irradiated seeds, which, they claim, support the need for labeling sprouts grown from seeds that have been irradiated; however, they failed to provide any additional data or information to substantiate their claim.

The Agency specifically discussed in the seeds for sprouting rule the labeling of irradiated seeds for sprouting and sprouts grown from such seeds (65 FR 64605 at 64606). The FDA evaluated the need for special labeling against the labeling provisions for food treated by ionizing radiation in § 179.26(c) (21 CFR 179.26(c)). Specifically, § 179.26(c) states that ''the label and labeling of retail packages of *foods* irradiated * * * shall bear the * * * logo along with either the statement 'Treated with radiation' or * * * 'Treated by irradiation.''' (emphasis added). Thus, the requirement applies only to the food that has been irradiated. It was noted in the seeds for sprouting rule that the irradiated article, the unsprouted seed, is not what is generally consumed and that the nutritional and flavor characteristics of the sprouts is based upon the fact that the irradiated seeds were grown into sprouts; therefore, sprouts grown from irradiated seeds do not require labeling as they are not the food that is being irradiated.

Additionally, neither Jonathan Sprouts, Inc., nor any of the other objectors that raised this point, provided any evidence that sprouts grown from irradiated seeds differ from sprouts grown from seeds that were not irradiated. An objector must make an adequate proffer of evidence to support its allegations and to show that they provide a basis on which to call into question the Agency's conclusions (§ 12.24(b)(2)). Therefore, the Agency is denying Jonathan Sprouts' objection.

V. Summary and Conclusion

Section 409 of the Federal Food, Drug and Cosmetic Act requires that a food additive be shown to be safe prior to marketing. Under § 170.3(i), a food additive is ''safe'' if ''there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.'' In the Agency's October 30, 2000, seeds for sprouting rule, FDA concluded that the studies conducted, based on its evaluation of the data submitted in the petition and other relevant material, that this use of irradiation is safe for its intended use in seeds for sprouting.

The petitioner has the burden to demonstrate the safety of the additive to gain FDA approval. However, once FDA makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (see section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act).

Despite their allegations, neither Public Citizen nor Jonathan Sprouts, Inc., has established that FDA overlooked significant information contained within the record in reaching its conclusion that the use of irradiation for microbial control of pathogens in seeds for sprouting is safe. In such circumstances, FDA has determined that the objections do not raise any genuine and substantial issue of fact that can be resolved by an evidentiary hearing (§ 12.24(b)). Accordingly, FDA is denying the requests for a hearing.

VI. References

The following references are on display in the Division of Dockets Management (HFA–303) Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, under Docket No. FDA–1999–F–0021 (formerly 1999F–2673) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum to file, FAP 4M4428, from David G. Hattan, Acting Director, Division of Health Effects Evaluation, dated November 20, 1997.
2. Taub, I.A. et al., ''Factors Affecting Radiolytic Effects In Food,'' *Radiation Physics and Chemistry,* 14:639–653, 1979.
3. WHO, ''Wholesomeness of Irradiated Food: Report of a Joint FAO/IAEA/WHO Expert Committee,'' World Health Organization Technical Report Series, No. 659, World Health Organization, Geneva, 1981.
4. WHO, ''Safety and Nutritional Adequacy of Irradiated Food,'' World Health Organization, Geneva, 1994.
5. Memorandum to the file, FAP 9M4673, from I. Chen, FDA, to J. Ziyad, FDA, dated February 28, 2000.
6. Diehl, J.F., ''Safety of Irradiated Foods,'' 2nd Edition, Marcel Dekker, New York, 1995.
7. Merritt, C., Jr., ''Qualitative and Quantitative Aspects of Trace Volatile Components in Irradiated Foods and Food Substances,'' *Radiation Research Reviews,* 3:353–368, 1972.
8. Memorandum to the file, FAP 9M4673, from K. Morehouse, FDA, to J. Ziyad, FDA, dated February 23, 2000.
9. Kylen, A.M. and R.M. McCready, ''Nutrients in Seeds and Sprouts of Alfalfa, Lentils, Mung Beans and Soybeans,'' *Journal of Food Science,* 40:1008–1009, 1975.
10. Diehl, J.F., ''Radiolytic Effects in Foods,'' pp. 279–357, in *Preservation of Food by Ionizing Radiation,* vol. I, E.S. Josephson and M.S. Peterson, eds., CRC Press, Boca Raton, FL, 1982.
11. Codex 1983, ''Codex General Standard for Irradiated Foods (CODEX STAN 106–1983)'' Codex Alimentarius Commission, Food and Agriculture Organization and World Health Organization, Rome, 1983.
12. WHO, ''High-Dose Irradiation: Wholesomeness of Food Irradiated With Doses Above 10 kGy,'' World Health Organization Technical Report Series, No. 890, World Health Organization, Geneva, 1999.

Dated: May 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–11391 Filed 5–10–12; 8:45 am]

BILLING CODE 4160–01–P

[3] It should be noted that the revisions of the Codex standards in 2003 do not impact this rulemaking.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 310

[Docket No. FDA–1978–N–0018] (Formerly Docket No. 1978N–0038)

RIN 0910–AF43

Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of compliance dates; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is delaying the compliance dates for the final rule for over-the-counter (OTC) sunscreen drug products that published in the **Federal Register** of June 17, 2011 (76 FR 35620). The final rule establishes labeling and effectiveness testing for certain OTC sunscreen products containing specified active ingredients and marketed without approved applications. It also amends labeling claims that are not currently supported by data and lifts the previously-published delay of implementation of the Drug Facts labeling requirements for OTC sunscreens. The 2011 final rule's compliance dates are being delayed because information received after publication of the 2011 final rule indicates that full implementation of the 2011 final rule's requirements for all affected products will require an additional 6 months. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: *Effective Date:* This final rule is effective June 18, 2012. The final rule published at 76 FR 35620 on June 17, 2011, remains effective June 18, 2012.

Comment date: Submit written or electronic comments on the delay of compliance dates by May 21, 2012.

Compliance Dates: The compliance dates for the final rule published at 76 FR 35620 on June 17, 2011, including the lifting of the delay of implementation date for 21 CFR 201.66 as published at 69 FR 53801, September 3, 2004, are delayed until December 17, 2013, for products with annual sales of less than $25,000, and until December 17, 2012 for all other products subject to the rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–1978–N–0018 (formerly Docket No. 1978N–0038) and RIN number 0910–AF43, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA–1978–N–0018 (formerly Docket No. 1978N–0038), and RIN 0910–AF43 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* insert the docket numbers, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Reynold Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5411, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 17, 2011, a final rule was published for OTC sunscreen products (hereafter referred to as ''2011 final rule''). The 2011 final rule established labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients and marketed without approved applications, to be codified in the Code of Federal Regulations (CFR) at § 201.327 (21 CFR 201.327) (which is effective June 18, 2012). It also amended § 310.545 (21 CFR 310.545) to classify as new drugs, requiring premarket approval, sunscreens labeled with certain claims (claims for ''instant protection'' or protection immediately upon application, or claims for ''all-day'' protection or extended wear claims citing a specific number of hours of protection that is inconsistent with the directions for application in § 201.327). Finally, it lifted the delay of implementation of the Drug Facts regulation, § 201.66 (21 CFR 201.66), published at 69 FR 53801, September 3, 2004, requiring those products to comply with § 201.66 on the same date as they would be required to comply with § 201.327 (76 FR 35620 at 35629). The 2011 final rule had an effective date of June 18, 2012, which was 1 year following publication of the final rule. For OTC sunscreen products with annual sales of $25,000 or more, the 2011 final rule had a compliance date of June 18, 2012. For OTC sunscreen products with annual sales of less than $25,000, the 2011 final rule had a compliance date of June 17, 2013.

The 2011 final rule explains why these effective and compliance dates were chosen (76 FR 35620 at 35623 through 35624). The primary reason for a 1-year effective date and compliance date for the majority of products was that FDA chose a simpler and less expensive testing method to demonstrate broad spectrum activity than had been originally proposed. Because a simpler testing method was chosen, it was projected that most OTC sunscreen drug products could be brought into compliance with the new testing and labeling requirements within 1 year.

Following publication of the 2011 final rule, a request to extend the period for implementation of the 2011 final rule by 6 months was submitted to FDA by The Personal Care Products Council (PCPC) and The Consumer Healthcare Products Association (CHPA), which are trade associations for the cosmetic and personal care products industry and the OTC drug products industry, respectively, in the United States (Ref. 1). PCPC and CHPA consolidated comments from its member companies in this submission. The submission provided several reasons, and supporting information, for requesting the additional time for implementation. Based on this submission, FDA is extending the compliance dates for the 2011 final rule, as explained in the paragraphs that follow.

II. Discussion of Rationale for Delay

FDA is delaying the compliance dates of the 2011 final rule by 6 months, to December 17, 2012, for products with sales of $25,000 or more, and until

December 17, 2013, for products with annual sales of less than $25,000. The 2011 final rule requirements are intended to ensure that OTC sunscreen products are used safely and effectively. Therefore, allowing adequate time for the 2011 final rule requirements to be fully implemented is in the interest of public health. Our reassessment of the time needed for full implementation of the 2011 final rule requirements supports delaying the compliance dates by 6 months.

FDA finds that the information provided by the PCPC/CHPA submission, describing the process for testing and relabeling sunscreen products, supports the requested extension of the time for compliance with the 2011 final rule. The submission included an operational timeline that detailed the numerous steps involved in implementation of the new labeling requirements for a given product, and included specific time estimates for the different stages of implementation (Ref. 1). The operational timeline's time estimates were calculated by taking the average of time estimates calculated by PCPC's and CHPA's member companies. The submission stated that complete implementation of new labeling could not be achieved by June 18, 2012, particularly for sunscreen products that: (1) Had complex label redesign issues and (2) required broad spectrum testing. Complex label redesign issues included contending with special production techniques to implement relabeling (e.g., glass or plastic bottles that require embossing), incorporating complete Drug Facts panel labeling, and coordinating relabeling of product lines with many variants. The submission also estimated that because of the substantial number of existing or new formulations that would need to undergo broad spectrum testing and the limited capacity of testing facilities, it would require approximately 10 months for industry to complete the broad spectrum testing for all products. The overall operational timeline provided in the submission indicates that testing and other necessary label redesign issues could not be completed for all products in time for labeling consistent with those test results to be applied to products by June, 2012, the original compliance date for sunscreens with annual sales of $25,000 or more.

FDA concurs that the operational timeline included in the submission supports extending the implementation period by an additional 6 months. One of our primary objectives in the 2011 final rule is to provide labeling that will enable consumers to identify and select sunscreen products that provide broad spectrum protection as well as a minimum sun protection factor (SPF) of 15. These sunscreens are particularly important for the public health because, in addition to helping prevent sunburn, sunscreens with a broad spectrum SPF value of 15 or higher, if used as directed with other sun protection measures, decrease the risk of skin cancer and early skin aging caused by the sun. If the timeline for implementation discourages manufacturers from conducting broad spectrum testing, and instead prompts them to apply the labeling that the final rule establishes for products that have not been established to offer broad spectrum protection, a major public health goal of the rule will be undermined. For this reason, granting manufacturers additional time to complete testing and relabeling is in the public interest. Also, implementation of § 201.66, the general Drug Facts labeling requirements, has been intended to be coordinated with the implementation of the substantive labeling changes necessitated by § 201.327, which provide the specific content for the Drug Facts panel for sunscreens. We therefore conclude that the implementation periods for these rules should remain coordinated.

We also conclude that extension of the compliance dates for § 310.545(a)(29)(ii) should likewise be extended because it is claims in labeling, and not formulation, that defines what sunscreens are subject to this provision of the 2011 final rule. The claims that would necessitate submission of a new drug application (NDA), as defined by that provision of the rule, are claims that would be in conflict with the labeling required by § 201.327. We believe that in many cases the relabeling of products to comply with § 201.327 will remove claims that would otherwise bring the sunscreen within § 310.545(a)(29)(ii). We therefore intend to revise the compliance dates to be codified in § 310.545(d)(40), so as to avoid requiring sunscreens that bear the indicated claims to be removed from the market before their relabeled replacements are ready.

We note that the PCPC/CHPA submission also stated that instituting a 6-month extension in the implementation period would be consistent with actions taken on previous FDA sunscreen rulemakings. The submission cited the 2007 sunscreen proposed rule (72 FR 49070 at 49073, August 27, 2007) and the 1999 sunscreen final rule (64 FR 27666 at 27686, May 21, 1999), where it was stated that complying with requirements in a sunscreen final monograph may require an implementation period of more than 1 year. The submission stated that FDA has delayed implementation of rules in the past when a delay is justified.

We acknowledge that implementation periods of more than 1 year were allowed for previous OTC sunscreen rulemakings and concur with the requested delay of implementation in light of the specific information submitted after the publication of the final rule, detailing specific reasons why additional time is required for all sunscreen drug products to achieve compliance. Because we cannot determine which particular products would be unable to comply, we are extending the compliance dates generally, but we nonetheless encourage manufacturers to act with diligence to bring products into compliance as soon as possible, so as to provide the public with the benefits of the new labeling. We have not altered the effective date of the regulation, and encourage manufacturers to introduce individual products bearing the new labeling as it becomes available, even in advance of the revised compliance date.

We find that there is adequate rationale to delay the compliance dates for the 2011 final rule. We are issuing this rule directly, without issuing a notice of proposed rulemaking or taking comments on this action, for good cause. Because manufacturers' plans depend on the date by which compliance is expected, and the original compliance date for most products is now imminent, we find that issuing notice and taking comments are impracticable, unnecessary, and contrary to the public interest with respect to this action. As already noted, without this extension of the time for implementation, manufacturers who do not anticipate being able to comply by the original compliance dates expressed in the final rule would be faced either with discontinuing distribution, or potentially confining themselves to the labeling for products that have not been established to be broad spectrum. This means that consumers would be deprived of the additional information to make informed choices regarding their sun protection options. With regard to § 310.545, in particular, we also find it is in the public interest to extend the compliance date prior to the effective date, to avoid the confusion that would likely ensue if the codified had already been incorporated into the CFR with the earlier compliance dates. Accordingly, 5 U.S.C. 553(b) and § 10.40(e)(1) (21 CFR 10.40(e)(1)) provide a statutory and regulatory basis for not issuing notice or taking comment

prior to implementing the delay of the compliance dates for the 2011 final rule. In accordance with § 10.40(e)(1), however, interested parties may submit comments on whether the extension of compliance dates set forth in this document should subsequently be modified or revoked.

III. Submission of Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Analysis of Impacts

The 2011 final rule includes a comprehensive examination of the economic impact of the 2011 final rule (76 FR 35620 at 35654 through 35657). A 6-month delay of the compliance dates for the 2011 final rule is unlikely to significantly affect the time or cost estimates made in that economic impact analysis. The 6-month delay allows additional time for testing and relabeling. However, the economic impact analysis in the 2011 final rule presumed that testing and relabeling could be fully implemented without the additional 6 months. Therefore, delaying the compliance dates by 6 months should not increase the time and cost estimates in the 2011 final rule.

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have determined that this final rule is not a significant regulatory action under Executive Order 12866. Consistent with Executive Order 13563, the approach taken here maintains ''flexibility and freedom of choice for the public,'' above all by providing ''information for the public in a form that is clear and intelligible.''

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We concluded that the 2011 final rule would have a significant economic impact on a substantial number of small entities. Our analysis of this economic impact is discussed at 76 FR 35620 at 35657. However, delaying the compliance dates of the 2011 final rule does not affect any of the numerical estimates made in our analysis.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. It is not expected that this final rule will result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this final rule is to delay the compliance dates for the 2011 final rule by 6 months. The delay of the compliance dates is based upon information received after publication of the 2011 final rule that indicates that full implementation of the 2011 final rule's requirements for all affected products will require an additional 6 months.

V. Environmental Impact

The Agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. ''Personal Care Products Council—Comment, FDA–2011–N–0449–0003, 10/06/2011,'' *http://www.regulations.gov.*

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 2. Section 310.545 is amended by revising paragraph (d)(40) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

* * * * *

(d) * * *

(40) December 17, 2012, for products subject to paragraph (a)(29)(ii) of this section. December 17, 2013, for products with annual sales less than $25,000.

Dated: May 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–11390 Filed 5–10–12; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 62

RIN 1400–AD14

[Public Notice 7875]

Exchange Visitor Program—Summer Work Travel

AGENCY: Department of State.

ACTION: Interim final rule with request for comment.

SUMMARY: The Department of State (Department) published an initial interim final rule with request for comment on April 26, 2011) (2011 IFR) to amend the regulatory requirements of the Summer Work Travel category of the Exchange Visitor Program. In this second interim final rule (2012 IFR), the Department expands upon and provides guidance on additional regulatory changes and bolsters portions of the regulations to both further to protect the health, safety, and welfare of Summer Work Travel Program participants and to reinforce the cultural exchange aspects of the Program to promote mutual understanding in accordance

with the Mutual Educational and Cultural Exchange Act of 1961. The Department has reviewed the comments submitted in response to the 2011 IFR, and this rule reflects those comments. Also, this 2012 IFR reinforces the cultural exchange aspect of the Program through the addition of a cultural component, and provides additional protection to program participants by describing types of job placements that are appropriate and by expanding the list of jobs prohibited under the Summer Work Travel Program. The enforcement of parts of this IFR is delayed until November 1, 2012.

DATES: This rule is effective May 11, 2012, with the exception of 22 CFR 62.32(h)(11) that will go into effect November 1, 2012. The Department will accept written comments from the public up to 60 days from July 10, 2012.

ADDRESSES: You may submit comments by any of the following methods:

- *Online:* Persons with access to the Internet may view this notice and provide comments by going to the regulations.gov Web site and searching on its RIN (1400–AD14) at: *http://www.regulations.gov/index.cfm.*
- *Mail (paper, disk, or CD–ROM submissions):* U.S. Department of State, Office of Designation, SA–5, Floor 5, 2200 C Street NW., Washington, DC 20522–0505.
- *Email: JExchanges@state.gov.* You must include the RIN (1400–AD14) in the subject line of your message.

FOR FURTHER INFORMATION CONTACT: Robin J. Lerner, Deputy Assistant Secretary for Private Sector Exchange, U.S. Department of State, SA–5, Floor 5, 2200 C Street NW., Washington, DC 20522–0505; phone (202) 632–2805; fax (202) 632–6442.

SUPPLEMENTARY INFORMATION:

Executive Summary

Statement of Need. In recent years, the work component of the Summer Work Travel Program has too often overshadowed the core cultural component necessary for the Program to be consistent with the Fulbright-Hays Act. In addition, there have been complaints regarding job placements, work conditions, and participant accommodations. As a result, the Department initiated a comprehensive review of the Summer Work Travel Program in mid-2010, and issued the 2011 IFR based on this review. However, events that occurred in the summer of 2011 confirmed to the Department that it needed to enhance its scrutiny of the Summer Work Travel Program and take additional steps to amend regulations to protect program participants.

The Department is keenly aware, however, that the salutary foreign affairs goals of the Exchange Visitor Program, including the Summer Work Travel Program can be seriously jeopardized, when even a single participant has a harmful or abusive exchange experience, or is inappropriately placed without due regard for the core cultural requirements and intended benefits of the Program. Therefore, through this second IFR, the Department seeks to continue: (i) Reforming the Summer Work Travel Program; (ii) ensuring that the Program better protects the health, safety, and welfare of program participants; and (iii) fortifying the Program's prestige as a world class U.S. public diplomacy initiative.

Statement of Legal Authority. The Exchange Visitor Program (of which the Summer Work Travel Program is one of 15 categories of program types) was authorized by the Mutual Educational and Cultural Exchange Act of 1961 (Pub. L. 87–256, 75 *Stat.* 527) (Fulbright-Hays Act or Act) and implemented through 22 CFR part 62. Enacted by the *87th United States Congress* on September 21, 1961, the Act's stated purpose was ''to increase mutual understanding between the people of the United States and the people of other countries by means of educational and cultural exchange; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations, and the contributions being made toward a peaceful and more fruitful life for people throughout the world. * * *'' In the half century since the Act's passage, millions of people—program participants, Americans with whom they interact, and friends and family of the participants with whom they share their experiences upon returning home—have benefitted from the mutual understanding and peaceful relations that can derive best from such person-to-person contact. The Summer Work Travel Program embodies and carries forward the stated purpose and intent of the Act.

Provisions of the 2011 IFR. The 2011 IFR presented four major changes (and several minor changes) to the Summer Work Travel Program regulations that were designed to strengthen sponsors' oversight of both their program participants and the third parties who assist them in performing the core administrative functions of the Exchange Visitor Program. Those changes were:

1. Sponsors were required to vet and confirm the validity of all host employers and fully vet all job offers;
2. Only Summer Work Travel Program participants from countries that participated in the Visa Waiver Program could depart their home countries without pre-placed jobs;
3. Sponsors were required to fully vet all third parties who they engaged to assist in performing certain enumerated core functions; and
4. Sponsors were required to contact active program participants on a monthly basis to monitor both their welfare and their geographical physical location.

However, in spite of these changes, events that occurred in the summer of 2011 confirmed the need to take additional steps to amend the regulations that safeguard program participants.

Changes to the 2011 IFR. Following the publication of the 2011 IFR, the Department reviewed comments received from 35 parties. Effective immediately, this rule makes further changes to some provisions introduced in the 2011 IFR to reflect those comments, clarify ambiguities, and make necessary corrections. These changes include:

1. The Department corrected two inadvertent changes to the regulations: Sponsors must continue to offer participants assistance in finding job placements starting one week (versus two) after participants initiate their job searches; and it reinserted language prohibiting employers from paying participants less than their American counterparts;
2. Sponsors are not required to maintain listings of bona fide job offers (but must offer participants reasonable assistance in finding new jobs);
3. Sponsors are not required to verify the Employee Identification Numbers (EIN) of host employers (although they must obtain them);
4. Sponsors must obtain evidence that potential host employers are registered to do business in the jurisdictions where participants will be placed;
5. Sponsors must input job titles and sites of activity in the Student and Exchange Visitor Information System (SEVIS) prior to participants' visa interviews (and not prior to issuing Forms DS–2019);
6. Host employers may not assist sponsors in the monthly monitoring of participants; and
7. Acknowledging the Department does not have jurisdiction over host employers, the ''host employer obligation'' section is renamed ''host

employer cooperation'' and refocused to urge sponsors to work only with host employers willing to make good faith efforts to comply with the requirements therein.

The provisions of the 2011 IFR, as amended by the 2012 IFR, are considered final upon publication of this 2012 IFR. The Department is not soliciting further notice and comment on these provisions.

New Provisions in the 2012 IFR. Additional changes to the Summer Work Travel Program regulations presented in the 2012 IFR allows the U.S. government to better regulate sponsors in order to protect participants, the program itself, and U.S. communities that support Summer Work Travel participants. The 2012 IFR implements new regulations to expand sponsors' obligations with respect to the cultural component mandated by the Act, clarify characteristics of jobs that are consistent with the purpose of the Act, identify jobs that are inconsistent with the purpose of the Act, and otherwise provide guidance to sponsors to ensure appropriate administration of the Summer Work Travel Program, with one exception, starting with the 2012 summer season. The 2012 IFR clarifies several issues that commenting parties raised:

1. The requirement that participants contact sponsors within ten days following their arrivals does not conflict with the requirement that sponsors validate SEVIS records within 30 days of participants' arrivals;

2. Individuals enrolled full time in on-line universities are not eligible for the program;

3. Sponsors and foreign entities cannot provide host employers cash or gift incentives (though they may host job fairs);

4. Sponsors must provide *itemized* annual cost schedules for all fees participants pay for program participation (including fees charged by foreign entities);

5. Sponsors must *terminate* (versus *end*) the programs of participants who do not comply with certain requirements that sponsors are obligated to enumerate during program orientation;

6. Sponsor outreach to participants must be answered in order for the contacts to be considered monthly monitoring;

7. Sponsors must annually vet host employers and third parties (foreign and domestic) and each season must reconfirm the number of jobs available with each host employer; and

8. Sponsors must vet initial, subsequent, and additional jobs before participants start work.

A significant enhancement presented in the 2012 IFR is the refocus of the program on the cultural experience of participants, which in recent years has been overshadowed by the goal of income production. In addition, the 2012 IFR makes changes to better protect the health, safety, and welfare of participants. To this end, the 2012 IFR makes several changes including adding the following requirements:

1. Sponsors must provide information to incoming participants explaining the cultural component of the Summer Work Travel Program, including guidance on how best to experience U.S. culture and/or descriptions of cultural opportunities that sponsors have arranged;

2. Job placements must be seasonal or temporary and must provide opportunities for participants to interact regularly with U.S. citizens and experience U.S. culture during the work portion (i.e., not travel portion) of their programs;

3. In addition to the job prohibitions expanded in the 2011 IFR, sponsors must not place participants:

a. With employers that fill non-seasonal or non-temporary job openings with participants with staggered vacation schedules;

b. In positions that require licensing or as operators or drivers of vehicles or vessels for which drivers' licenses are required regardless of whether they carry passengers or not;

c. In jobs for which there is another specific J visa category;

d. In positions requiring work hours that fall predominantly between 10:00 p.m. and 6:00 a.m.;

e. In positions declared hazardous to youth by the Secretary of Labor at Subpart E of 29 CFR part 570;

f. In positions that require sustained physical contact with other people and/or adherence to the Center for Disease Control and Prevention's Universal Blood and Body Fluid Precautions guidelines (e.g., body piercing, tattooing, massage, manicure);

g. In positions that are substantially commission-based and thus do not guarantee that participants will be paid minimum wage in accordance with federal and state laws;

h. In positions involved in gaming and gambling that include direct participation in wagering and/or betting;

i. In positions in chemical pest control, warehousing, catalogue/online order distribution centers;

j. In positions with travelling fairs or itinerant concessionaires; and

k. After November 1, 2012, in positions in the North American Industry Classification System's (NAICS) Goods-Producing Industries occupational categories industry sectors 11, 21, 23, 31–33 (set forth at *http://www.bls.gov/iag/tgs/iag_index_naics.htm*).

Sponsors are also required to take more active roles in ensuring that participants have access to suitable, affordable, and safe housing and reliable and affordable transportation between their residences and worksites.

The 2012 IFR also includes new protections for U.S. workers. Each season, sponsors must confirm that the host employers with which they intend to place participants:

1. Will not displace U.S. workers at worksites where they place program participants;

2. Have not experienced layoffs in the past 120 days; and

3. Do not have workers on lockout or on strike.

The Department seeks comment on the new provisions presented in the 2012 IFR.

Background

On April 26, 2011, the Department of State (Department) issued an interim final rule with request for comment modifying the regulations of the Summer Work Travel category of the Exchange Visitor Program (2011 IFR) (see 76 FR 23177). Those regulations became effective on July 15, 2011. The Department has reviewed the comments of 35 parties, and this rule modifies the regulations to reflect those comments. Effective immediately, this rule makes further changes on an interim final basis to the Summer Work Travel Program regulations and requests comments.

The Department is aware of and appreciates the efforts the sponsor community has undertaken to adjust in a short timeframe to the new regulatory model presented in the 2011 IFR. It is imperative, however, to amend further the Summer Work Travel Program regulations before the next large wave of participants arrives. The changes included in the 2012 IFR bear most directly on the health, safety, and welfare of the participants and reinforce the cultural exchange aspects of the Program to promote mutual understanding in accordance with the Mutual Educational and Cultural Exchange Act of 1961, as amended; 22 U.S.C. 2451 *et seq.* (Fulbright-Hays Act or Act). The Department will propose other modifications to the Summer Work Travel Program later in 2012 through a Notice of Proposed Rulemaking (NPRM).

The focus of the 2012 IFR is three-fold. First, the Department will introduce new requirements to remind sponsors of the centrality of the cultural component of the Summer Work Travel Program and, in this regard, prescribe characteristics of certain job placements and types of cultural activities that can appropriately promote mutual understanding, a core purpose of the Fulbright-Hays Act. Second, the Department will discuss changes it adopted in the 2011 IFR in light of the comments it received and will announce the final regulatory changes associated with that effort. Finally, it will implement new regulations, most of which are effective with the publication of this rule, to expand sponsors' obligations with respect to the cultural component, clarify characteristics of jobs that are consistent with the purpose of the Act, identify jobs that are inconsistent with the purpose of the Act, and otherwise provide guidance to sponsors to ensure appropriate administration of the Summer Work Travel Program starting with the 2012 summer season, during which roughly 80 percent of all program participants come to the United States.

Summer Work Travel Program. The Summer Work Travel Program allows foreign post-secondary students (mostly between the ages of 18 and 30) to come to the United States—for a maximum of four months—during their major academic breaks to travel and work in largely unskilled jobs. For nearly 50 years, this category of the Exchange Visitor Program has been a part of U.S. public diplomacy efforts, under the auspices of the Fulbright-Hays Act. As reflected in a Statement of Policy dated March 28, 1996 (see 61 FR 13760), this category of the Exchange Visitor Program was implemented to open the program to those persons who were otherwise financially unable to visit the United States. During the initial 50 years of the program, more than one million foreign students have participated in the Sumer Work Travel Program. The popularity of this Program—both with participants and U.S. embassies and consulates abroad as part of their public diplomacy efforts—arises from the participants' ability to enjoy cultural exchange experiences while offsetting at least a portion of their travel costs through temporary employment in the United States. However, despite its popularity, the Program is not without challenges.

In recent years, the work component has too often overshadowed the core cultural component necessary for the Summer Work Travel Program to be consistent with the intent of the Fulbright-Hays Act. Also, the Department learned that criminal organizations were involving participants in incidents relating to the illegal transfer of cash, the creation of fraudulent businesses, and violations of immigration law. There also were increasing numbers of complaints related to the Program, such as reports of improper or unsafe job placements, fraudulent job offers, post-arrival job cancellations, inappropriate work hours, and problems regarding housing and transportation.

In response, the Department initiated a comprehensive review of the Summer Work Travel Program in mid-2010, intended both to enhance the Department's governance of the designated Summer Work Travel Program sponsors and to tighten the regulations these sponsors must follow. To this end, the Department has been re-evaluating the regulations and making changes to the Summer Work Travel Program regulatory model. In January 2011, following a series of meetings with law enforcement agencies, employers, industry associations, and sponsors, the Department adopted a pilot program for Summer Work Travel Program participants from certain countries with a higher prevalence of problems (Pilot Program). The second step to safeguarding and strengthening the Summer Work Travel Program was incorporating Pilot Program concepts as key elements of the 2011 IFR. The 2011 IFR presented four major changes (and several minor changes) to the Summer Work Travel Program regulations that were designed to strengthen sponsors' oversight of both their program participants and third parties who assist them in performing core functions that are inherent in the administration of the Exchange Visitor Program (i.e., participant screening, selection, orientation, placement, and monitoring; and the promotion of mutual understanding). First, sponsors were required to vet and confirm the legitimacy of all host employers and fully vet all job offers. Second, only Summer Work Travel Program participants from countries that participated in the Visa Waiver Program could depart their home countries without pre-placed jobs. Third, sponsors were required to vet fully all third parties whom they engaged to assist in performing certain enumerated core functions. Finally, sponsors were required to contact active program participants on a monthly basis to monitor both their welfare and their geographical physical location. The incorporation of these concepts into the overall Summer Work Travel Program regulations in the 2011 IFR formally ended the separate Pilot Program.

Events that occurred in the summer of 2011 confirmed the Department's initial assessment that it needed to enhance further its scrutiny of the Summer Work Travel Program and take additional steps to amend regulations that safeguard program participants. While the 2011 IFR established procedures for confirming the existence of proposed job placements, it did not provide guidance for assessing the suitability of job offers or preventing the displacement of U.S. workers. In August, the Department learned of inappropriate job placements for Summer Work Travel Program participants who were staffing a packaging plant. Summer Work Travel Program participants: (1) Were concentrated in single locations for long hours in jobs that provided little or no opportunity to interact with U.S. citizens; (2) were exposed to workplace safety and health hazards; and (3) were subjected to predatory practices through wage deductions for housing costs. These circumstances informed the Department that additional regulatory changes were necessary in order better to regulate the sponsors to protect participants, the program itself and U.S. communities that support Summer Work Travel participants.

As part of the overall Program review, in September 2011, the Department announced and initiated on-site reviews of 14 Summer Work Travel Program sponsors. (See 76 FR 59182 (Sept. 23, 2011).) In addition to assessing sponsor compliance with the current regulations, these reviews allowed the Department to consult with sponsors regarding the impact of the 2011 IFR on their operations. The Department completed these site visits and is in the process of analyzing the results.

Next, the Department announced a cap on the maximum number of Summer Work Travel Program participants for calendar year 2012 and a moratorium on the designation of additional organizations as sponsors in the Summer Work Travel Program category. (See 76 FR 68808 (Nov. 7, 2011)) Peaking at just over 153,000 participants in 2008, the Summer Work Travel Program will proceed for the near future at a level not to exceed 109,000 participants annually. The cap is sponsor-specific and based on the number of participants for each sponsor with program start dates between January 1 and December 31, 2011 (i.e., for the calendar year). The Department intends to retain these restrictions until it is confident that the program

regulations are sufficient to remedy identified concerns.

In November 2011, the Department hosted an open meeting with the sponsor community, including the Alliance for International Educational and Cultural Exchange. On December 13, 2011, the Department issued Guidance Directive 2011–05. See *http://j1visa.state.gov/wp-content/uploads/2012/01/2011-GD05-12_13_2011Summer-Work-Travel-A-Cultural-Experience.pdf.* The Department used these forums to announce its heightened scrutiny of the Summer Work Travel Program and its intention to publish new program regulations through additional rulemakings, including the 2012 IFR. The Department invited comments on both occasions. A number of sponsors criticized the Department for opting to modify the Summer Work Travel Program regulations through another interim final rule. The Department concluded that it must issue another interim final rule in order to promptly improve its existing regulatory framework given the potential impact on individual participants' health, safety, and well-being. The use of traditional notice and comment procedures would not allow for implementation of these important safeguards prior to the summer of 2012. Accordingly, the Department is making certain rule changes in the 2012 IFR and will publish additional modifications through NPRM procedures later this year. To further monitor and ensure the health, safety, and welfare of program participants, the Department of State is in discussion with the Department of Homeland Security and other federal agencies and enforcement authorities regarding the appropriateness of an information-sharing memorandum of understanding (MOU). Such MOU would establish guidelines and a protocol for the exchange of, analysis of, and appropriate action on, information indicating possible criminal abuse or misuse of the Summer Work Travel Program.

Cultural exchange. The Summer Work Travel Program is intended to allow foreign nationals, who could not otherwise afford to visit the United States as tourists or students, the opportunity to experience U.S. culture by defraying part of their travel and living expenses by working while in the United States. Over time, however, some sponsors, participants, and host employers lost sight of the central cultural exchange focus of the Act. Additionally, many participants viewed the Program as an opportunity simply to work in jobs that allow them to earn more money than they would in their home countries. The Program's evolution did not comport with the intentions of the Act or the purpose of international exchange programs to increase mutual understanding. Accordingly, the 2012 IFR refocuses the Summer Work Travel Program towards the U.S. cultural experience and away from its income and labor opportunities.

The cultural dimension of the Summer Work Travel Program experience is essential to all participants. Sponsors must consider the cultural component in all placement decisions. Rather than mandating specific types of cultural programs, however, the Department offers as guidance two examples of ways sponsors can meet the cultural component requirement. Sponsors could organize activities that acquaint participants with recognized features of U.S. culture and history (e.g., national parks, historic sites, major cities, scenic areas) and/or offer activities that engage participants with the communities in which they work and live. A core presumption underlies the Department's renewed focus on the cultural component of the Summer Work Travel Program: solely work-based cultural exposure is insufficient. Only those sponsors that demonstrate that their Summer Work Travel Program participants engage in cultural exchange activities outside of their places of employment will qualify to be considered for biannual re-designation.

Summer Work Travel Program participants historically have been placed in a wide variety of jobs in all 50 states and the District of Columbia. The Department recognizes that it would be difficult, at best, to prescribe specific cultural activities that the current 49 designated sponsors must offer to their program participants. With this in mind, the Department changes the Summer Work Travel Program regulations to ensure that participants are placed in jobs that are conducive to experiencing U.S. culture. To that end, the 2012 IFR enumerates criteria that sponsors must meet when approving job offers, and it expands the list of prohibited placements. More specifically, it requires sponsors to ensure participants have specific opportunities to interact with U.S. citizens and experience U.S. culture outside their workplaces.

Many sponsors already provide cultural opportunities for their Summer Work Travel Program participants. The Department commends those sponsors and encourages them to share their ''best practices'' when commenting on the 2012 IFR. Sponsors must focus their placements on jobs that are clearly appropriate under these new regulations and that offer opportunities to interact with U.S. citizens. Sponsors must also enable regular interaction with Americans during work and non-work hours. For example, a significant majority of Summer Work Travel Program participants work in vacation areas—in or near beach communities, amusement parks, and campgrounds in the summer and at or around ski resorts in the winter. These service industry jobs provide routine opportunities for participants to interact with U.S. citizens—both as customers and co-workers.

Although the new placement criteria and prohibitions together establish that the participants' jobs must provide them interactions with U.S. citizens (e.g., co-workers, customers), such exposure during the course of the work-day will not satisfy the cultural requirement of the Summer Work Travel Program. Sponsors must intentionally plan and implement cultural activities to augment this quotidian exposure in order to be in compliance with the purpose of the Act. The Department understands that the more widely participants are geographically dispersed, however, the more difficult it may be for sponsors to arrange and/or monitor directly these mandatory cultural events. Accordingly, the Department reassesses both the types of third parties that sponsors may use to assist them in performing core programmatic functions, e.g., promoting mutual understanding, as well as the specific functions third parties may perform.

Specifically, this 2012 IFR allows sponsors to enlist third parties to oversee cultural activities designed to expose participants to U.S. citizens and U.S. culture. That is, domestic third parties—including employers—may assist sponsors in ''the promotion of mutual understanding'' by arranging sightseeing tours, trips to sporting events, local community activities, etc. As the 2012 IFR modifies the 2011 IFR to allow only sponsors to complete the monthly monitoring requirement, third party arranged cultural activities are not a substitute for the monthly monitoring requirement. The Department reminds sponsors that they are responsible for the actions of third parties they may engage to fulfill the cultural component requirement and that such actions will be imputed to the sponsors. The Department seeks comment on sponsors' provision of cultural opportunities, especially with respect to best practices that can be shared with the sponsor community.

Comment analysis received on the 2011 IFR. Thirty-five parties submitted comments to the 2011 IFR. Of those, 12 parties were designated sponsors and one was an association that represents designated sponsors. Most of the commenting parties recognized both the value of the Summer Work Travel Program and the need for modified regulations. However, both sponsors and small businesses who hire Summer Work Travel Program participants stated that the regulatory changes were administratively burdensome. Sponsors argued that the Department had understated the cost to implement the changes. Two research organizations and two individual citizens recommended shutting down or sharply reducing the Program's size. The 14 non-sponsor participants who supported the Summer Work Travel Program included small businesses, an amusement park industry association, and individual citizens. The small businesses noted that they often cannot find sufficient numbers of qualified Americans to fill the positions where J–1 exchange visitors are traditionally placed. The Department has carefully considered all comments and has accordingly made modifications to the regulations proposed in the 2011 IFR as described below.

Purpose. One commenting party remarked on redundant language about program duration in the ''Purpose'' section of the regulations, and the Department has accordingly eliminated that language. However, the refocus of the cultural component of the Program has been added to this section. The Department has modified the language both to emphasize the cultural aspect of the Program and to call attention to the types of jobs that are appropriate for Summer Work Travel participants.

Duration. Seven parties commented about the length and timing of participants' Summer Work Travel programs. Several of them urged the Department to allow participants to stay past Labor Day, as seasonal employers may require their continued presence in order to meet this final concentration of demand. Others commented that the Department had adopted countrywide dates for program participation without regard for individual schools' academic calendars. Some disputed the requirement that final year students be restricted to those schedules, citing no reason for them to have to return home.

Other than final-year students who are expected to return home to start their careers, participants are expected to return to their studies following participation in the Summer Work Travel Program. Thus, these dates must necessarily reflect academic calendars—without regard for host employers' specific needs. To facilitate appropriate participation in the Summer Work Travel Program, the Department has established country-specific program start and end dates according to the academic year calendars of each country's universities. The Department may modify the list of country-specific program dates should a particular need arise (e.g., a shift in the academic year in a particular country). The Department notes that it does not allow final year participants to extend their programs beyond the country-specific end dates.

Participant screening and selecting. The 2011 IFR reintroduced the concept of ''core'' programmatic functions (see 61 FR 13760 (published March 28, 1996)). Several parties commented on the concept of core functions, seeking further definition and clarification. The six core programmatic functions which are differentiated from more general business administrative functions are: participant screening, selection, orientation, placement, monitoring; and the promotion of mutual understanding. While the Department requires sponsors to undergo the rigorous designation and re-designation processes, it has correspondingly less influence and oversight over third parties who assist sponsors in the administration of their programs. Accordingly, the new Summer Work Travel Program paradigm prevents wholesale delegation of sponsor duties to parties unknown to the Department both by limiting the functions third parties can perform and by delineating steps sponsors must undertake to confirm the bona fides of such third parties. The Department continues to impute the actions of all third parties to the sponsors that engage them.

The 2011 IFR states that ''sponsors are solely responsible for adequately screening and making the final selection of their program participants. * * *'' The Department has since realized that third parties should not assist sponsors in the core function of selecting participants, and it modifies the regulations accordingly. However, the Department broadly construes activity of ''screening'' to include recruiting, interviewing, assessing English language proficiency, etc. While foreign entities may screen participants, sponsors remain solely—and ultimately—responsible both for setting the standards for screening and for making final participant selection, based upon information foreign entities gathered as part of the screening process.

English language. Two parties commenting on the 2011 IFR remarked about the importance of participants being proficient in English (e.g., safety of students and success of program depend on English language skills). In the 2011 IFR, the Department allowed sponsors to interview participants via video conference, thereby providing sponsors with a low-cost means of interviewing participants ''in person.'' Despite this change, the Department continues to notice a significant number of Summer Work Travel Program applicants who are denied visas because their English proficiency is not sufficient to participate in the Program. Since the lack of adequate English ability may put participants at risk during their exchanges, the 2012 IFR establishes more explicit English proficiency standards that applicants to the Summer Work Travel Program must demonstrate to their sponsors' satisfaction. Specifically, applicants must have sufficient English proficiency not just to perform their jobs, but also to navigate daily life; read and comprehend program materials; fully understand their job benefits and responsibilities and their rights and protections; and know how to obtain assistance, if necessary. The Department reminds sponsors that the addition of video-conferencing as an interview tool provided them a cost-effective means of conducting these interviews themselves should they find foreign entities not fully capable of accurately assessing applicants' English proficiency. The Department will interpret inordinately high visa rejection rates because of insufficient English language proficiency as an indication that sponsors are not sufficiently screening potential applicants.

Accredited academic institutions. The 2011 IFR also added the requirement that participants in the Summer Work Travel Program be ''enrolled full-time and pursuing studies at *accredited* post-secondary *academic* institutions located outside the United States'' (emphasis added). One party commented on this change, specifically with respect to the absence in the language of a requirement that these institutions have a formal campus of the ''bricks and mortar'' variety, and not be on-line schools. The Department did not intend to open the door to students enrolled in purely Internet-based schools. Summer Work Travel participants must have an academic pull back in their home countries (or in the foreign countries where they are studying) that requires them to leave the United States at the end of their academic breaks. Accordingly, the Department clarifies that the post-secondary institutions in

which participants must be enrolled to participate in the Summer Work Travel Program must be classroom based, in addition to being accredited and academic in nature.

Participant orientation. The Department adds to the list of required orientation materials and information that sponsors must provide Summer Work Travel Program participants before they depart their home countries. Sponsors must explain the importance of the cultural component of the Summer Work Travel Program. They must provide guidance on how best to experience U.S. culture and/or describe cultural opportunities they have arranged. For participants with pre-placed jobs, sponsors must provide details on job offers and information about housing and transportation to and from work. Additionally, sponsors must inform participants that they risk program termination if they (1) fail timely to report their arrival and/or changes of residence; (2) start work at un-vetted jobs; and/or (3) fail timely to respond to sponsors' monthly monitoring outreach contacts. Many commenting parties opined that it would be difficult to get college students to respond to sponsors' outreach. The Department disagrees. By providing sufficient orientation and a clear understanding of the conditions of program participation at the outset, sponsors should be able to gain the cooperation of their participants to comply with program rules. The Department encourages sponsors that already achieve this level of cooperation from their participants to share their best practices with the Department during the comment period.

Consequences of non-compliance by participants. With respect to how to respond to participants who fail to meet the obligations enumerated above, the preamble accompanying the 2011 IFR stated: ''As a point of clarification of existing regulations, sponsors are obligated to end the exchange programs of participants who do not report their arrival within ten days following the program start date or who do not report changes in their U.S. addresses or sites of activity within ten days of such moves.'' (76 FR 23177, 23180) (April 24, 2011)) During the on-site reviews, at association meetings, and in comments filed in response to the 2011 IFR, many sponsors inquired whether they should simply ''end'' programs of non-compliant participants' programs or actually terminate their status in the Student and Exchange Visitor Information System (SEVIS). The Department recognizes that this statement needs further clarification. Sponsors must inform participants that their non-compliance will result in their termination from the program, and that program termination puts at risk their ability to travel to the United States in the future.

Many commenting parties expressed concern that the requirement that participants contact their sponsors within ten days of arrival in the United States conflicted with the requirement that sponsors validate participants' records in the SEVIS within 30 days. The Department clarifies that this new notification requirement does not change the requirement in 22 CFR 62.70(b) that sponsors update SEVIS records within 21 days of learning of changes of current U.S. addresses, or the requirement in 22 CFR 62.70(d) that sponsors validate SEVIS records of Summer Work Travel Program participants within 30 days of their program start dates. These are obligations of sponsors with respect to SEVIS maintenance; the new regulatory language imposes an obligation on participants to report their arrivals and any address changes promptly to their sponsors. Since implementing the 2011 IFR, however, the Department has determined that participants cannot change or add jobs independently. If they wish to change or add jobs, they must first consult with their sponsors who must verify the terms and conditions of prospective jobs and fully vet potential host employers. This change has made unnecessary the previous requirement that participants inform sponsors within ten days of changing jobs. Accordingly, the Department modifies the regulations to make clear that the participants' ten-day notification requirement applies only to reporting participants' arrivals and changes of residences (including securing initial residences). It further clarifies that sponsors must inform participants that they may not start, change, or add jobs before their sponsors have vetted the host employers and the terms and conditions of the jobs pursuant to 22 CFR 62.32(n). The Department requires sponsors to act promptly (i.e., within 72 hours) to verify this information and to report back to the participants the results of such action.

The Department considers participants starting work before their sponsors fully vet their jobs to be engaged in unauthorized employment and reminds sponsors of 22 CFR 62.16(b), which states: ''An exchange visitor who engages in unauthorized employment shall be deemed to be in violation of his or her program status and is subject to termination as a participant in an exchange visitor program.'' The requirement that program participants not change jobs without permission from their sponsors in no way suggests that participants must remain in unsuitable positions such as those that are not consistent with written job offers or in other ways do not meet the expectations of participants or the purpose of the Act. The Department expects that sponsors will not unreasonably withhold their assistance or permission for participants who have valid reasons for wishing to change or add jobs.

Employees at will. One sponsor sought clarification of the requirement that sponsors provide pre-placed participants with information about the ''contractual obligations'' between the participants and their employers. This party asked what kind of information was required and how a ''contract'' could exist given that most participants—like their U.S. counterparts in these jobs—would be considered ''employees at will.'' The Department agrees that Summer Work Travel Program participants are employees at will, but nevertheless requires sponsors to inform participants about the terms and conditions of their job offers. This creates a degree of transparency that can ensure that the participants' expectations are in line with the jobs and conditions that they will encounter upon their arrival in the United States. The Department is developing a Summer Work Travel Program Job Placement Form (i.e., Form DS–7007) to capture the information necessary for sponsors to demonstrate that they have fully vetted potential jobs (e.g., the name and address of the host employer, the hourly wage, benefits, the range of hours per week the participants likely will work, whether the host employer has arranged housing, and if so, its cost to the participant). The Department published the form in the **Federal Register** and sought comment on its design (see 76 FR 72996 (Nov. 28, 2011)). Until such time as the DS–7007 Form is finalized and adopted, as a ''best practice,'' sponsors may voluntarily begin using forms similar to the Form DS–7007 for informing participants about the details of their vetted jobs.

Cultural component. Sponsors are required to inform participants prior to their departure from their home countries about the importance of the cultural aspects of the Summer Work Travel Program. They must provide specific guidance on how participants can avail themselves of cultural opportunities in general as well as identify specific activities that the

sponsors intend to arrange to further promote cultural exchange. Sponsors must screen out those applicants whose interests in the Summer Work Travel Program predominantly appear focused on earning income. Accordingly, the Department will view the lack of documented evidence of participants' cultural activities required by Summer Work Travel Program regulation as, among other things, a deficiency by sponsors adequately to screen and orient program participants. The Department seeks comment on the Program's refocus on the cultural component and encourages sponsors to share their best practices.

Participant placement. In the 2011 IFR, the Department established a new process by which sponsors must vet both potential job offers and potential host employers. The Department's experience with this requirement—both for the Pilot Program this past summer and this most recent winter session—has demonstrated the benefits of this new model. No sponsor commenting on the 2011 IFR objected to this new requirement; accordingly, the Department makes no substantive changes to the job and employer vetting requirements. It does clarify, however, that sponsors must vet potential host employers annually and that prior to each season, sponsors must confirm the number of jobs each host employer seeks to fill with program participants. The Department clarifies, however, that placement is one of the core functions that sponsors may not enlist third parties to perform. In this context, placement means matching particular participants with specific job opportunities. In other words, third parties (foreign and domestic alike) may provide *sponsors* with leads for potential jobs, but sponsors must determine the suitability of individual participants for specific jobs and make all placements.

In the 2011 IFR, the Department prohibited sponsors and foreign entities from providing incentives to employers to accept program participants for job placements. In the 2012 IFR, the Department clarifies that participant placement is the sole responsibility of sponsors, i.e., foreign entities may not match participants with available jobs. The Department, however, realizes that despite this restriction, both U.S. and foreign third parties could play an ancillary role in finding job placements, e.g., by informing sponsors or participants (who find their own jobs) about potential job openings. Accordingly, the 2012 IFR expands the prohibition to include the provision of incentives to employers by all third parties acting on behalf of sponsors. While the regulations continue to prohibit such third parties from actually placing participants, the Department wishes to ensure that third parties or sponsors in no way provide potential host employers with incentives to accept any participants for job placements.

With respect to the definition of ''incentives'' in this context, seven commenting parties urged the Department to clarify that it does not intend to prohibit sponsors from funding travel expenses for employers of Summer Work Travel Program participants to international job fairs that provide hiring entities the opportunity to meet their prospective workers. The Department understands that the cost of travel, accommodations, meetings, and meals would be included in the cost of such job fairs. It considers job fairs to be opportunities for potential host employers to meet their prospective employees and, therefore, not incentives to hire particular sponsors' participants. Likewise, the Department does not seek to prohibit meetings between prospective or current host employers and sponsors at mealtimes. However, the Department does consider gifts, cash payments, and trips paid for by sponsors that do not include opportunities to meet prospective participants to be prohibited ''incentives'' to host employers.

Confirm all jobs. Under the terms of the Pilot Program, sponsors were required to confirm all jobs prior to participants' departures from their home countries by verifying both the bona fides of the potential employers and the terms and conditions of the job offers themselves. In the 2011 IFR, this requirement was extended to all participants from non-Visa Waiver Program countries. In comments on the 2011 IFR, one party urged the Department to allow participants from Visa Waiver Program countries to begin work as soon as they obtained job offers and allow sponsors five days to vet the employers and the jobs in order to allow participants to start work immediately. Theoretically, this could apply also to participants from non-Visa Waiver Program countries who wanted to change or add jobs or to participants from Visa Waiver Program countries both under those circumstances and in the case of their initial employment. The Department respectfully rejects this recommendation because it believes it will cause unnecessary confusion as to which participants could start unverified jobs and under what conditions. Once participants have arrived in the United States and secured job offers, sponsors must vet initial, subsequent, and additional jobs within 72 hours. The Department requires sponsors to have sufficient staff and resources to ensure the jobs of all participants to whom they offer exchange programs are timely and fully vetted. The Department seeks comment on potential barriers to sponsors meeting this 72 hour deadline.

Obligation to work with participants seeking new or additional jobs. The 2011 IFR proposed new requirements for vetting both host employers and the terms and conditions of individual job offers. The Department adopts those provisions with limited change. Although the text of the regulation has been slightly restructured to provide more clarity, the only substantive change the Department makes is in response to comments on the 2011 IFR and during the on-site reviews. There was widespread objection to retaining the requirement that sponsors maintain rosters of bona fide job listings for participants seeking job placements. Some commented that not only is it difficult to keep these lists updated, this requirement is also an anachronism in the Internet era. The Department agrees and eliminates the requirement that sponsors maintain such lists of available jobs. Instead, the Department now explicitly requires sponsors to offer reasonable assistance to participants seeking additional or subsequent jobs (regardless of whether participants were initially direct-placed or self-placed). The 2011 IFR incorrectly changed from one to two weeks the amount of time non-pre-placed participants must attempt to find work before obtaining assistance from their sponsors. The Department clarifies that sponsors are expected to undertake reasonable efforts to assist non-pre-placed participants (i.e., those from Visa Waiver Program countries) who have not found suitable employment within one week of commencing job searches.

The Department recognizes that there are many reasons that participants may be unsatisfied with their initial jobs and that the expectations of some participants may differ from the reality of their placements. Although sponsors are required to make reasonable efforts to find replacement jobs for participants, under certain circumstances, it would be appropriate for sponsors to end (not terminate) programs of participants for whom subsequent suitable jobs cannot reasonably be arranged. While participants who end the work portion of their programs early may travel in the United States before returning home,

those with terminated programs may not.

New criteria for appropriate job placements. The Department adds new criteria that sponsors must consider when determining the suitability of job placements. In addition, it expands the list of prohibited job placements. The goal is further to ensure the placement of participants in appropriate jobs that provide them better opportunities to experience U.S. culture and to ensure that participants work in environments that are safe and appropriate for the Exchange Visitor Program. Jobs must be seasonal or temporary in nature. Employment is of a seasonal nature when the required services or labor are traditionally tied to a season of the year by an event or pattern, and employers require labor levels above and beyond existing worker levels. Employment is of a temporary nature when employers' needs for duties to be performed are short-term, a one-time occurrence, a peak load need, or an intermittent need. It is the nature of employers' needs, not the nature of the duties that is controlling.

Sponsors must place participants only in jobs that offer opportunities to interact routinely with U.S. citizens and experience U.S. culture. Sponsors may place participants only in those jobs that adhere to the participant placement criteria listed in 22 CFR 62.32(g)(4–6), which among other things includes prohibited jobs found at 22 CFR 62.32(h). Sponsors must use extra caution when placing participants in positions with host employers in lines of business that have been associated with trafficking in persons (e.g., modeling agencies, housekeeping, janitorial services). When sponsors follow the previously cited regulations and guidance, the result will be job placements that:

- Do not have the effect of displacing U.S. workers, especially young U.S. citizens (18–25 years old), a group that is currently experiencing high unemployment levels;
- Do not overly concentrate program participants or isolate program participants from interactions with U.S. citizens, both of which will diminish the cultural exchange component of the program; and
- Permit participants to work alongside U.S. citizens in the same or similar jobs.

Sponsors may place participants with employment or job placement agencies only under the following three circumstances: First, participants must be employees of and paid by the staffing agencies; second, staffing agencies must provide full-time, primary, on-site supervision of the participants; and third, staffing agencies must effectively control the work sites, e.g., have hands-on management responsibility for the participants. If these three conditions are not met, staffing agencies are not fulfilling the role of employers, and sponsors may not place participants with them.

Program exclusions. Notwithstanding its development of this new guidance for identifying appropriate jobs, the Department retains and enhances the list of prohibited positions that have traditionally been incorporated in Summer Work Travel Program regulations. As the Department's concern for the health, safety, and welfare of participants and the integrity of the Summer Work Travel Program remain of paramount importance, it views this approach to job selection guidance as both prudent and necessary.

First, the Department clarified that sponsors cannot place participants in jobs as operators or drivers of vehicles or vessels, even if they are not carrying passengers. It also articulated additional examples of prohibited jobs in the adult entertainment industry. Moreover, due to concerns about participants' health, safety and welfare, the Department further expanded this list to include jobs that have already been declared by the Secretary of Labor to be hazardous to youth; jobs that require adherence to the Center for Disease Control and Prevention's Universal Blood and Body Fluid Precautions guidelines and/or require sustained physical human contact; jobs in warehouses; and chemical pest control jobs. Further, jobs that fall under the North American Industrial Classification System (NAICS) Goods-Producing Industries occupational categories industry sectors 11, 21, 23, 31–33 are prohibited, specifically: Natural Resources and Mining (including Agriculture, Forestry, and Fishing and Hunting as well as Mining, Quarrying, and Oil and Gas Extraction); Construction; and Manufacturing. This prohibition is the only portion of the 2012 IFR that will be effective, not with publication of the 2012 IFR, but on November 1, 2012.

Two other job positions are now excluded. Sponsors may not place participants in positions for which the compensation is substantially commission-based because they do not guarantee that participants will be paid minimum wage in accordance with federal and state standards. Also, positions with traveling fairs or itinerant concessionaires are also now prohibited due to health and safety concerns associated with a nomadic lifestyle, as well as the resulting difficulty in tracking the locations of such participants in SEVIS. Finally, as part of its effort to refocus the program on its cultural purpose, the Department further expands the list of excluded positions in the 2012 IFR to include types of employment that are incompatible with a cultural exchange program: including positions requiring work hours that fall predominantly between the hours of 10:00 p.m. and 6:00 a.m. and positions in catalogue/online order distribution centers. Consistent with Executive Order 13563, and its particular emphasis on the importance of public participation, the Department requests comments on these expanded job prohibitions in this interim final rule.

The Department recognizes that in light of the timing of this interim final rule, the immediate implementation of the NAICS prohibitions at this date may cause serious economic hardship for certain employers, sectors, or locations for the immediate summer 2012 season. For this reason, the Department is adopting a phased approach and implementation of those specific prohibitions will not go into effect until November 1, 2012, after the immediate summer season. On or before that date, sponsors that place participants in these jobs, must either end the participants' programs or place the participants in permitted jobs.

The Department emphasizes that all other provisions of the 2012 IFR are effective immediately upon publication. This means that the programs of participants placed this summer in jobs that will be prohibited starting November 1, 2012 are still subject to all program regulations during the upcoming summer season. For example, sponsors must ensure those positions provide participants opportunities to interact routinely with U.S. citizens during the day and after, do not fall predominantly between the hours of 10:00 p.m. and 6:00 a.m., and do not prevent participants from actively and routinely taking part in cultural activities. In addition, such placements may not create over-concentration of participants in any one location, or displace U.S. citizen workers at the specific worksites.

Housing and transportation. The regulations adopted in the 2011 IFR required sponsors to advise only participants from Visa Waiver Program countries how to find appropriate and reasonably priced housing. The Department now amends the regulations to include all Summer Work Travel Program participants. When evaluating the suitability of potential jobs, sponsors must consider the availability,

affordability, and suitability of local housing and transportation. When host employers do not offer housing and transportation or participants do not wish to avail themselves of employer-provided housing and transportation, sponsors must actively and immediately assist Summer Work Travel Program participants in arranging suitable, affordable, and safe housing, and ensuring that reliable and affordable transportation between their residences and work sites is available. To be considered safe, housing must, at a minimum, meet all applicable local laws and regulations, including with respect to ventilation, utilities, and occupancy rates. If it is difficult for sponsors to identify appropriate housing and/or transportation under certain circumstances, this should signal the sponsors to search for other jobs in other locations. The Department seeks comment on the expanded roles of sponsors in ensuring the availability of appropriate housing and transportation.

Often, host employers provide housing and/or transportation to program participants and reduce their hourly pay or otherwise deduct from their pay to cover the cost of such housing and/or transportation. In these cases, job offers must explicitly describe such arrangements and specify the market value of the housing and/or transportation. In this way, it is clear whether the participants are being compensated in compliance with program regulations, including compliance with state wage requirements and section 531 of the Fair Labor Standards Act (FLSA), which requires that such deductions be voluntary and not include a profit to the employer or to any affiliated person.

Forms DS–2019. Four parties objected to the requirement that sponsors enter the host employer sites of activities and job titles in SEVIS *prior to* issuing Forms DS–2019. One party commented that this requirement was unworkable because it forces employers to commit months before knowing their summer employment needs. It recommended that, instead, the language be changed to require collection of employment information in SEVIS *before* applicants' visa interviews. Others expressed concern that employers do not know the sites of activity prior to the preparation of Forms DS–2019, and one stated that participants are often assigned specific job titles only after they report to work.

The Department disagrees with respect to participants from non-visa waiver countries. Sponsors must vet their potential employers as set forth at 62.32(n), confirm the terms and conditions of their job offers, and input complete and correct data into SEVIS prior to issuing Forms DS–2019 to participants from non-visa waiver countries. In the rare cases where sponsors do not know the sites of activity, they may initially enter the employers' main addresses in the site of activity fields, noting that such information will change, and update SEVIS prior to the visa interview. Clearly, such job and employer information is available for participants from visa-waiver countries only if they opt to secure placements prior to departing their home countries—in which case, they will be treated as participants from visa-waiver countries for purposes of determining when such information must be entered into SEVIS. Accordingly, sponsors can issue Forms DS–2019 for non-pre-placed participants from visa waiver countries prior to entering any of this information into SEVIS. However, sponsors must always vet employers and job offers prior to entering the data into SEVIS.

Participant compensation. Sponsors must ensure that host employers fairly compensate participants for their work. In the 2011 IFR, the Department adopted the requirement that Summer Work Travel Program participants, regardless of age, be compensated at the higher of the applicable state minimum wage or the federal minimum wage. One party commented that the broader and more protective language of the prior regulations (i.e., ''shall ensure that participants receive pay and benefits commensurate with those offered to their American counterparts'') should be retained. The Department notes that this language was unintentionally dropped from the 2011 IFR and hereby reinserts it. Another commenting party expressed concern that the regulations did not include the minimum wage exemption for jobs with amusement and recreational establishments found in the FLSA. By reinserting the dropped language, the regulations implicitly recognize the minimum wage exemption of the FLSA for such placements. If a sponsor has reason to suspect that a participant is not being compensated in accordance with Federal, State or local law, the sponsor must contact the appropriate authorities, including, but not limited to the U.S. Department of Labor's Wage and Hour Division.

Monitoring. There are numerous reasons for sponsors to stay in regular and direct communication with their participants. First, this type of contact allows sponsors to check on participants' health, safety, and welfare. Also, it reinforces the primacy of the sponsor/participant relationship in the Summer Work Travel Program so that participants with concerns about their programs will reach out to their sponsors for assistance should they need it. Further, it provides sponsors with the opportunity to confirm that they have the participants' correct ''Current U.S. Addresses'' and ''Sites of Activity'' listed in SEVIS, so they may maintain accurate SEVIS records in the interest of National Security. It also allows sponsors to confirm that participants are enjoying the mandatory cultural experiences. For these reasons, the 2011 IFR expanded the obligations of sponsors to monitor their program participants by requiring personal contact with all participants on a monthly basis. Sponsors must document such monthly contacts, which can be in-person, by telephone, or via email exchange. Many sponsors commenting on the 2011 IFR objected to having to actually reach participants to meet this obligation, suggesting that it would be difficult if not impossible to compel participants to respond to sponsors' outreach. The Department disagrees and subsequently clarifies that although broadcast or individual texts, emails, or voice messages, for example, may be considered attempts to *initiate* contact with participants, participants must respond to communications in order for such contacts to be considered complete. Sponsors must terminate the programs of participants who exhibit a pattern of failing to respond to the monthly monitoring. Accordingly, sponsors must not place participants in locations where it is difficult for them to access the normal forms of communications.

Sponsors' use of third parties. One commenting party urged the Department to allow foreign entities to participate in the monitoring function of participants, stating that foreign entities provide native language support, and the parents of participants appreciate their supportive roles. The Department recognizes the critical role that foreign entities can play in reaching out to participants when unusual circumstances require clear communication, and it clarifies that these regulations in no way prohibit foreign entities from contacting participants and/or their parents. Such contacts, however, do not count as part of the sponsors' monthly monitoring requirement. The Department does not allow host employers or any other third party to assist in conducting monthly monitoring. If program participants are having problems with their employers or the conditions of their jobs, allowing employers to assist in monthly

monitoring effectively denies participants' access to neutral advocates. In sum, sponsors may not delegate their monthly monitoring responsibilities to third parties, but must themselves initiate, complete, and document monthly contacts with all program participants.

With renewed focus on the cultural component of the Summer Work Travel Program and the understanding that sponsors often place participants throughout the United States, the Department has determined that sponsors may have third parties assist them in the core programmatic function of promoting mutual understanding. That is, sponsors may engage third parties to arrange local activities, sightseeing trips, or other events that allow participants to interact with U.S. citizens and/or learn about U.S. culture. Sponsors may wish to work together to offer joint activities. Sponsors must vet these domestic third parties according to the requirements set forth in Sec. 62.32(n).

Vetting third parties (foreign entities). The 2011 IFR also required sponsors to vet all foreign entities (i.e., overseas agents or partners) that assist them in fulfilling the core programmatic functions that may be conducted outside the United States and to maintain current listings of such parties in a new ''Foreign Entity Report.'' Specifically, sponsors must obtain proof of these entities' business licenses, disclosures of previous bankruptcies or pending legal actions, three written references, summaries of the entities' prior J–1 experience, criminal background check reports, and copies of sponsor-approved advertising materials. After sponsors have successfully vetted foreign entities, they must provide the Department with this information to allow the Department to update the *Foreign Entity Report.* Although applicants do not need to work with foreign entities, they may not work with those foreign entities who are not included in the *Report.* If any material information (e.g., contact information, financial status, criminal backgrounds of principals, relationship with sponsor) changes, sponsors must promptly provide this information to the Department.

Eight parties commented on these requirements, voicing almost unanimous concern that it would be too expensive to maintain English translations of foreign entities' marketing materials, especially given the Internet-focus of today's advertising environment. They requested that instead, sponsors approve the major marketing themes of their foreign entities. The Department disagrees. The foreign entities' initial outreach to potential program participants sets the stage for participants' expectations about the Summer Work Travel Program. Sponsors must be aware of what the foreign entities are posting on web sites, communicating through social media, and distributing in printed materials to ensure the information conforms to the purpose and intent of the program and meets regulatory requirements. It is important, for example, that the cultural exchange aspects of the program are accentuated, and that students' expectations about how much money they can earn are realistic.

During its on-site reviews, the Department had the opportunity to assess several sponsors' compliance with foreign entity verification requirements for the winter 2011–2012 season. Overall, the Department found that sponsors were readily able to obtain almost all the requested documents without undue cost or burden. Accordingly, the Department makes only minor changes to the provisions enumerated in this section of the regulations to correct for errors in the text that allowed foreign entities to select participants and failed to require annual vetting of foreign third parties.

Although not included in the regulations, the preamble to the 2011 IFR mentioned that sponsors must obtain notarized financial statements to demonstrate the financial solvency of potential foreign entities (See 76 FR 23177–23179). Two parties commenting on this language suggested that it would be difficult to obtain notarized financial statements and recommended that the Department require sponsors to obtain copies of bank statements instead. The Department does not believe that a single view of an entity's bank account provides sufficient evidence of its financial viability, while it believes notarized statements are a step in fraud prevention. The Department also clarifies that sponsors must annually update the records and credentials of the foreign entities they engage to help administer their Summer Work Travel Programs. Additionally, pursuant to 22 CFR 62.32(p)(2), the Department takes this requirement one step further and now requires sponsors to inform the Department when and why particular foreign entities are no longer under contract with them.

Vetting third parties (domestic entities). The 2011 IFR limited the domestic entities that could assist sponsors in performing core programmatic functions to host employers of participants. However, the broad range of structured and planned cultural events that can satisfy the cultural component requires flexibility with respect to the types of third parties sponsors can engage. For example, sponsors may partner with individuals who voluntarily assist in arranging local community events or major international corporations in the tourism line-of-business. As a result, there can be no one-size-fits-all process for vetting such third parties.

Accordingly, sponsors who engage business entities to provide cultural events or activities for which participants must pay (either directly or through the sponsors) must vet these entities according to the standards required for host employers set forth in the 2011 IFR and clarified in the 2012 IFR. In addition, they must enter into written agreements with such parties, and these agreements must explicitly describe the activities or events and itemize all costs. Private individuals or local groups (e.g., local consortia created to assist with the assimilation of Summer Work Travel Participants into the community, including church groups) that do not charge for participation need not be similarly vetted or enter into such written agreements. For this purpose, the Department would not consider, e.g., participants buying their own tickets to or food at local sporting events to be paying for participation, even if an individual or group made the arrangements. Sponsors should engage in assisting the provision of cultural events only with local individuals or groups that are known and reputable in the community.

The 2011 IFR requires that sponsors directly contact potential employers to verify key information as well as utilize publicly available information to confirm the existence and legitimacy of the potential host employers. Nine parties commented on this proposed rule change, with most of them either seeking clarification of the requirement that they verify potential host employers' Employer Identification Numbers (EINs) or opposing altogether the requirement to obtain EINs. One party recommended that the Department alternatively require sponsors to obtain copies of employers' current business licenses. The Department agrees and replaces the requirement that sponsors verify EINs with the requirement that they obtain proof that the businesses (e.g., corporations, partnerships) are authorized to operate in the state or jurisdiction. Such information is generally available from the Web sites of each state's Secretary of State. Copies of such registration documents should

sufficiently demonstrate that potential host employers are active and registered businesses in the locations where they will place participants.

Commenting parties sought guidance on what constitutes sufficient verification of host employer's worker's compensation coverage. First, sponsors must be aware of current state-specific requirements. Second, sponsors must obtain each host employer's workers' compensation policy identification number and a copy of the policy's Cover Page and/or Deck Sheet, confirming that the coverage is sufficient and active during the period of placement. Third, sponsors must determine whether the host employer has been recently sanctioned by the U.S. Department of Labor's Occupational Safety and Health Administration or Wage and Hour Division. Sponsors can check the Department of Labor's sanctioned list at: *http://ogesdw.dol.gov/.* Sponsors should hesitate to place participants with recently sanctioned employers.

One sponsor inquired whether there were certain conditions under which verification of an employer would be unnecessary (e.g., a previously vetted host employer or a host employer with whom the sponsor has worked for more than two years). The Department understands that many sponsors place program participants with the same host employers year after year. However, the cost and effort required to reconfirm the bona fides of past host employers are modest enough to warrant annual reconfirmation of all organizations' basic information. Also, the Department has observed too many job offers that were used in the summer and again in the winter season even though those host employers had no need for winter seasonal employees. Accordingly, the Department hereby modifies the regulations to require sponsors to vet host employers annually, and each season to verify the actual number of job placements available.

Host employer cooperation. The 2011 IFR also added a new section on host employer obligations. Nine parties commented on these new regulations, noting that the Department has no jurisdiction over employers, rendering unenforceable this entire new section of the rules. There also was concern about the inability of host employers to guarantee that participants would work a certain number of hours each week. Some commented that many seasonal and temporary jobs are dependent upon weather and customer demand, and employers do not guarantee U.S. summer workers a minimum number of hours. While the Department acknowledges these comments, it believes that sponsors should work only with employers who agree to make good faith efforts to comply with certain terms of employment. Accordingly, the Department changed the title of the section ''Host employer obligations'' to ''Host employer cooperation,'' thereby removing language suggesting it has jurisdiction over employers and has placed the obligation on sponsors to work only with those employers who would voluntarily commit to comply with these requirements.

With respect to ensuring participants are working sufficient hours to cover their basic expenses and meet their program expectations, sponsors should avail themselves of the monthly contact with participants to inquire about their job satisfaction and financial state. If conditions are such that participants simply are not earning enough money to cover their basic expenses, it is incumbent upon the sponsors to assist them in finding new or additional jobs.

Reporting requirements. Three parties opposed the Department's requirement that sponsors submit semi-annual placement reports. They contended that there is no value in identifying second or subsequent jobs or that the information is already available in SEVIS. The Department disagrees: SEVIS does not retain such information. Moreover, the Department believes that the more carefully sponsors screen participants and match their expectations to vetted job placements, the less frequently participants will change jobs, and such improved screening will be reflected in these reports. Accordingly, it retains this requirement to monitor participant job change rates and other program statistics.

Annual price lists. In the 2011 IFR, the Department adopted a requirement that written agreements between sponsors and foreign entities contain annually updated price lists. During the on-site reviews, Department staff reviewed many such sponsor agreements and determined that the inconsistent formats sponsors used to present program costs made it necessary for the Department to request information in a more standardized format. Accordingly, the Department has qualified this requirement so that sponsors specify the itemized costs that participants must pay to both foreign agents and sponsors to participate in the Summer Work Travel Program. Recent criticism of the program has included alleged exorbitant costs that program participants must pay to work in minimum wage jobs. The Department requests this information in order to protect participants, sponsors, and the integrity of the program.

Cultural exchange. While legitimate employment is an important component that defrays a portion of participants' program costs, it is neither the only element nor the primary element of the J–1 Exchange Visitor Program. Instead of merely lining up summer jobs for participants, sponsors must also consider—at the outset of any job placement consideration—the availability of housing and transportation, as well as the location of the position and the opportunities for cultural activities and community engagement. The balance between work time and free time, including the nature of the work itself and the opportunities for interaction with U.S. citizens during the workday, are also key considerations.

With this in mind, sponsors must place students in jobs that provide daily and ongoing interaction with U.S. citizens. Additionally, sponsors must ensure that participants have opportunities to engage in cultural exchange outside of work. During the biannual re-designation of sponsors as well as in the day-to-day oversight and monitoring of program sponsors, the Department will look specifically for evidence that sponsors are actively facilitating or offering non-work cultural opportunities for participants. Clearly, sponsors should consider the accessibility of cultural opportunities as an important factor in determining whether specific jobs are suitable for program participants. Implementation of cultural activities is further facilitated by group excursions to sporting events, establishing local volunteer networks that pair exchange visitors with local citizens, or otherwise making intentional efforts to integrate program participants into local communities. Finally, as noted above, sponsors may engage third parties to assist in providing this cultural component to their program participants.

Sponsors are not permitted to use cultural opportunities associated with the participants' employment to fulfill this requirement (e.g., amusement park visits are not acceptable cultural offerings for participants working at amusement parks). Registering participants on publicly available listserves of events is not sufficient by itself to meet this requirement; nor does the Department consider exclusively on-line interactions to be satisfactory cultural offerings. How well sponsors develop and implement the program's cultural component will carry significant weight in the Department's biannual re-designation process for

sponsors. The Department will presume that participants' significant non-participation in organized cultural activities is caused by inadequacies in the sponsors' cultural offerings, their inability to adequately calibrate participants' work/non-work experiences, and/or sponsors' failure to select participants who are seeking cultural exchange.

Sponsors are permitted to use cultural offerings as part of the required monthly contact with participants as long as any issues affecting the participants' health, safety, and welfare identified through such contacts are promptly and appropriately addressed. Sponsors should maintain evidence of participants' attendance in cultural events in their program files (e.g., event sign-up lists or emails confirming attendance at cultural events, signed and executed agreements with local organizations for volunteer service opportunities, cultural or educational excursions, group participation in cultural events).

Regulatory Analysis

Administrative Procedure Act

The Department of State is of the opinion that administration of the Exchange Visitor Program, including the Summer Work Travel Program, is a foreign affairs function of the U.S. Government and that rules implementing this function are exempt from Sec. 553 (Rulemaking) and Sec. 554 (Adjudications) of the Administrative Procedure Act (APA). As reflected in the Fulbright-Hays Act, the purpose of such programs is to increase mutual understanding between the people of the United States and those of other countries, ''unite us with other nations'', and ''to promote international cooperation''. Pursuant to law, policy, and longstanding practice, the Department of State has supervised either directly or through private sector program sponsors or grantee organizations, those foreign nationals who come to the United States as participants in exchange visitor programs, one of which is the Summer Work Travel Program. Summer Work Travel participants come to the United States from over 190 countries and when problems occur in a program such as this, foreign governments often directly engage the Department of State regarding the treatment of their nationals, regardless of who is responsible for the problems.

The Department emphasizes that many provisions of this interim final rule—indeed, the majority—reflect careful consideration of public comments received on a previous interim final rule, issued on April 26, 2011. Those provisions have been subject to detailed comments and this interim final rule has greatly benefited from those comments. At the same time, some provisions of this interim final rule are new. Some of these provisions will be enforced immediately, but others will not be enforced until November 1, 2012.

The Department has two overriding purposes for issuing this interim final rule. One purpose is to put in place urgently needed measures to protect the health, safety, and welfare of foreign nationals entering the United States to participate in the Summer Work Travel Program for a finite period of time (up to four months) and then return to their countries of nationality or last legal permanent residence upon completion of their programs.

The need for such efforts was made evident by a situation where Summer Work Travel participants were placed in nightshift jobs requiring long work hours in a packing warehouse and did not have free time available or the ability to interact daily with Americans, an experience in its totality that is contrary to a cultural exchange program. It is critical that Summer Work Travel sponsors currently planning for the summer of 2012 cycle of Summer Work Travel participants are now informed by regulation that exposure to such placements, and other jobs contrary to a cultural exchange program, are now strictly prohibited henceforth, starting with the summer 2012 cycles of Summer Work Travel participants. Failure to act swiftly and decisively with an interim final rule to protect the health, safety, and welfare of these program participants will have direct, foreseeable, and substantial adverse effects on the foreign affairs and relations of the United States.

The incidents were sufficiently of concern to cause the Department to engage in outreach to concerned officials from foreign affairs ministries around the world both to assuage them about our response to those incidents and to reaffirm the Department's intent to continue the Summer Work Travel program, but with necessary repairs (as was done in recent discussions the Department had with the governments of four of the largest countries sending Summer Work Travel participants). In short, a number of foreign governments have unequivocally informed the Department that they regard this program as important to their bilateral relationship with the United States and also important to their nationals who seek to participate in that program. Participating countries, therefore, look to the Department to keep the program alive but to fix it in a way that helps protect their nationals.

The second overriding purpose of this interim final rule is to help restore the Summer Work Travel program to its original *raison d'être* as a U.S. public diplomacy program intended to promote international cultural understanding in line with the overall purposes of the Fulbright-Hays Act, as discussed above. These two overriding goals are mutually reinforcing and provide the requisite foreign affairs function basis on which to adopt this interim final rule. Although the Department is of the opinion that this interim final rule is exempt from the rulemaking provisions of the APA, the Department is aware of the importance of public comment consistent with Executive Order 13563 and is publishing this rule as an interim final rule, with a discretionary 60-day provision for public comment and without prejudice to its judgment that the Exchange Visitor Program is a foreign affairs function. As noted above and discussed below, certain provisions of this interim final rule will not be enforced immediately, and will be delayed until November 1, 2012; comments are specifically invited on those provisions.

In addition, and without prejudice to its determination that the function discussed herein is a foreign affairs function of the United States, the Department also finds that there is ''good cause'' under 5 U.S.C. 553(b) and (d) for forgoing prior publication of an NPRM and for making this interim final rule effective upon publication, for the reasons summarized in this analysis, above, and explained more fully in the preamble.

Small Business Regulatory Enforcement Fairness Act of 1996

This interim final rule is not a major rule as defined by 5 U.S.C. 804 for the purposes of Congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). This interim final rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets.

Unfunded Mandates Reform Act of 1995

This interim final rule will not result in the expenditure by State, local and

tribal governments, in the aggregate, or by the private sector, of $100 million in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Regulatory Flexibility Act/Executive Order 13272: Small Business Impacts

Since this interim final rule (2012 IFR) is exempt from 5 U.S.C. 553, and no other law requires the Department of State to give notice of such rulemaking, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) and Executive Order 13272, Sec. 3(b). However, to better inform the public as to the costs and burdens of this rule upon designated program sponsors, the Department notes that the 2012 IFR will affect the operations of 49 corporate, academic, and tax-exempt program sponsors designated by the Department to conduct Summer Work Travel Programs. Further information follows.

Numbers of Small Businesses

Of the 49 currently designated Summer Work Travel Program sponsors, 33 sponsors have annual revenues of less than $7 million. These 33 small program sponsors accounted for approximately 36,000 of the 109,000 Summer Work Travel Program participants in 2011.

Prohibited Job Placements

The 2012 IFR specifically expands the list of prohibited job placements (at 22 CFR 62.32(h) *Program Exclusions*) to now include: positions declared hazardous to youth by the Secretary of Labor at 29 CFR 570.50 through 570.72; positions that require sustained physical contact with other people and/or adherence to the Center for Disease Control and Prevention Universal Blood and Body Fluid Precautions guidelines (e.g., body piercing, tattooing, massage, manicure); positions that are substantially commission-based and thus do not guarantee that participants will be paid minimum wage in accordance with federal and state standards; positions in the North American Industry Classification System's (NAICS) Goods-Producing Industries (set forth at *http://www.bls.gov/iag/tgs/iag_index_naics.htm)*, specifically NAICS Sectors 11, 21, 23, and 31–33: Natural Resources and Mining (including Agriculture, Forestry, and Fishing and Hunting as well as Mining, Quarrying, and Oil and Gas Extraction); Construction; and Manufacturing (e.g., industrial food processing); positions requiring work hours that fall predominantly between the hours of 10 p.m. and 6 a.m.; positions directly involved in gaming and gambling that include direct participation in wagering and/or betting; positions in chemical pest control, warehousing, or catalogue/online order distribution centers; and in positions with travelling fairs or itinerant concessionaires.

Collectively, these positions accounted for approximately eight percent (8%) of all Summer Work Travel Program placements in 2011. A single large program sponsor, which voluntarily terminated its Summer Work Travel Program designation in 2012, sponsored approximately 40% of 2011 participants placed in jobs prohibited by the 2012 IFR. Of the remaining placements last year in prohibited jobs, 24% were sponsored by small program sponsors. The Department estimates the cost of transferring participants scheduled for prohibited jobs to new placements at approximately $6,000 to $18,000 (one to three man hours at $20 per hour for the approximately 300 new positions to be arranged) for the 24 sponsors that made placements last year that will be prohibited by the 2012 IFR.

The Department notes that there will be some indirect impact in the short-run on the U.S. businesses that have historically employed Summer Work Travel Program participants in positions prohibited by the 2012 IFR. However, the Department is not imposing any direct regulatory requirements on these U.S. businesses.

Cultural Requirement

The 2012 IFR requires program sponsors to ensure that all participants have opportunities to interact regularly with U.S. citizens and experience U.S. culture during the work portion of their Summer Work Travel Programs and to participate in organized events, trips, or other activities outside of work. The Department estimates that the new cultural component requirement will cost, on average, $20 per participant, or approximately $2.2 million for the program. The Department notes that the actual cost of this requirement is likely less than $20 per participant: Many sponsors already provide such cultural activities for their participants and a significant majority of Summer Work Travel Program participants work in touristic areas where such activities may be organized for less than this estimated cost. The Department also emphasizes that it desires the cost of the cultural component not to be a burden on sponsors, and reiterates the number and variety of ways this requirement may be achieved. The Department accordingly estimates that approximately $720,000 of the cultural component cost of the 2012 IFR would fall upon small program sponsors. Collectively, the 2012 IFR will impose new costs of no more than $738,000 on the 33 small program sponsors. These costs as a percentage of small sponsor revenue are as follows: for 26 sponsors, the cost of these new requirements are between one and five percent (1–5%) of their annual revenues; for six sponsors the cost of these new requirements are between five and ten percent (5–10%) of their annual revenues; and for one small sponsor, the cost of these new requirements is approximately 20% of its annual revenue.

The Department determines that costs of the 2012 IFR are not significant to 26 of the 33 small program sponsors. The Department thus certifies that it does not believe that these regulatory changes will have a significant economic impact on a substantial number of small entities.

Executive Order 13563 and Executive Order 12866

As discussed above, the Department is of the opinion that the subject of this rulemaking constitutes a foreign affairs function of the United States, and thus is exempt from the provisions of Executive Order 12866. The Department has nevertheless reviewed this rulemaking to ensure its consistency with the regulatory philosophy and principles set forth in Executive Orders 12866 and 13563. The Department of State does not consider this interim final rule to be a ''significant regulatory action'' under Executive Order 12866, Sec. 3(f), *Regulatory Planning and Review,* and Executive Order 13563. However, to better inform the public as to the costs and benefits of this rule, the Department presents a discussion below.

Affected Population. The Department estimates this rule will affect 49 currently designated Summer Work Travel Program sponsors hosting a maximum of 109,000 participants. These sponsors are responsible for the individuals, many between the ages of

18 and 25, while in the Summer Work Travel Program. Sponsors provide the necessary information, support, and guidance for program participants. Although sponsors will be provided with professional automony regarding how they incorporate the requirements presented in the 2012 IFR, the Department estimates sponsors may still incur costs due to the rule.

Costs. Implementation of certain of the provisions set forth in the 2012 IFR may result in costs for the sponsors—those provisions are: implementation of placement prohibitions, implementation of a cultural requirement for program participants, and implementation of additional vetting, reporting, and record keeping requirements.

Prohibited Job Placements. This IFR prohibits certain jobs that sponsors may already have selected for participant placements. The cost of finding replacement jobs will be minimal for the prohibitions that do not become effective until November 1, 2012. For the category of jobs that are immediately prohibited based on concerns for health, safety and welfare, participants already placed in these jobs will need to be re-located to new placements. The Department estimates that number to be no more than 300 and has calculated the cost of transferring participants scheduled for those jobs to be approximately $6,000 to $18,000 (one to three man hours at $20 per hour times 300) for the 24 sponsors that made placements last year that will be prohibited by the 2012 IFR.

Cultural Component. The 2012 IFR requires program sponsors to ensure that all participants have opportunities to interact regularly with U.S. citizens and experience U.S. culture during the work portion of their Summer Work Travel programs and to participate in organized events or other activities outside of work. The Department estimates that the new cultural component requirement will cost an average of $20 per participant for up to 109,000 participants; or approximately $2.18 million annually for the program.

Vetting, Reporting, and Recordkeeping. The 2012 IFR places additional vetting, reporting, and recordkeeping requirements on sponsors. The Department calculates that the new requirements may entail up to two additional hours of work per placement for Summer Work Travel sponsors that include an additional half hour for participant orientation; one additional hour towards third party screening, vetting and monitoring; and an additional half hour for the recordkeeping of the cultural component that each Summer Work Travel participant receives. The Department estimates that half of the participating sponsors already incorporate these additional requirements into their business practices. The Department estimates the costs for vetting the host employers and participant placements for all Summer Work Travel sponsors at $2.18 million [½ × (2 hrs. × $20/hr. × 109,000 participants)].

Total Costs. The Department estimates that total costs to sponsors from implementation of the 2012 IFR requirements are estimated at $4.37 to $4.38 million in the first year. Recurring costs for the 2012 IFR requirements are estimated at $4.36 million for the cultural component of the program and the additional vetting, reporting, and recordkeeping component of the program.

Benefits. The 2012 IFR is a continuation of efforts the State Department is implementing based on a comprehensive review of the Summer Work Travel Program. The Department issued the 2011 IFR based on this review. However, events that occurred in the summer of 2011 confirmed to the Department that it needed to enhance its scrutiny of the Summer Work Travel Program and take additional steps to amend regulations to protect program participants. Several foreign governments and entities complained to the Department about job placements, work conditions, and participant accommodations. Additionally, in recent years, the work component of the Summer Work Travel Program has too often overshadowed the core cultural component necessary for the Program to be consistent with the Fulbright-Hays Act.

The changes included in the 2012 IFR bear most directly on the health, safety, and welfare of the participants and serve to reinforce the cultural exchange aspects of the program to promote mutual understanding in accordance with the Fulbright-Hays Act. These changes are expected to protect/improve the health, safety, and welfare of participants by reducing the number of improper or unsafe job placements, fraudulent job offers, post-arrival job cancellations, inappropriate work hours, and problems regarding housing and transportation. Additionally, these changes are designed to help ensure participants are properly compensated, thereby helping to defray their travel costs.

The cultural dimension of the Summer Work Travel Program experience is essential to all participants. The changes in the 2012 IFR require sponsors to consider the cultural component in all placement decisions. However, rather than mandating a specific type of cultural program, the Department offers flexibility in implementing this requirement. This cultural component is essential to promoting cultural exchanges with foreign governments. A number of foreign governments have unequivocally informed the Department that they regard this program as important to their bilateral relationship with the United States and also important to their nationals who seek to participate in that program. Participating countries, therefore, look to the Department to keep the program alive but to fix it in a way that helps protect their nationals. These changes help accomplish this goal.

The changes in the 2012 IFR will allow the United States government to better regulate the sponsors in order to protect participants, the program itself and U.S. communities that support Summer Work Travel participants. Sponsors are also required to take more active roles in ensuring that participants have access to suitable, affordable, and safe housing and reliable and affordable transportation between their residences and worksites. These changes will help ensure the health, safety, and welfare of participants as well as promote the intent of the Fulbright-Hays Act through cultural exchanges.

Executive Order 12988

The Department of State has reviewed this interim final rule in light of Sec. 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Orders 12372 and 13132

This regulation will not have substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this interim final rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. Executive Order 12372, regarding intergovernmental consultation on federal programs and activities, does not apply to this regulation.

Paperwork Reduction Act

The information collection requirements contained in this interim final rule (2012 IFR) are pursuant to the Paperwork Reduction Act, 44 U.S.C. chapter 35 and OMB Control Number

1405–0147, Form DS–7000. As part of this rulemaking, the Department is seeking comment regarding the additional administrative burden placed on sponsors due to the corresponding requirements for the sponsors to maintain additional records in the administration of their programs (*see* 22 CFR 62.10(f)).

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Recording, Reporting, and Data Collection Requirements Under 22 CFR part 62.

(3) *Agency form number:* DS–7000.

(4) *Affected public:* This is an expansion and continuation of an existing information collection utilized by the Bureau of Educational and Cultural Affairs in its administration and program oversight of the Exchange Visitor Program (J–Visa) under the provisions of the Mutual Educational and Cultural Exchange Act, as amended. The Department seeks comment from Summer Work Travel Program sponsors and other persons directly involved in the administration of the Summer Work Travel Program.

(5) Change to information collected by the Department of State: The existing Placement Report and Foreign Entity Report data collections are current collections required by all Summer Work Travel sponsors, and due to electronic reporting, do not impose any further recordkeeping burden. The 2012 IFR requires Summer Work Travel sponsors to submit annual price lists for all foreign entities to the Department, which is expected to place a minimal additional administrative burden on the 49 currently designated Summer Work Travel program sponsors. The Department believes that the additional regulatory requirements for documenting interviews, monthly contact with participants, and vetting host employers are already a standard business practice; however, the new requirements will bring all sponsors into conformity with program administration and will add a minimal administration burden as well.

Based on the current 2011 Foreign Entity Report, Summer Work Travel sponsors are working with approximately 960 foreign entities. The Department requires Summer Work Travel sponsors to conduct thorough vetting and institute formal agreements with each third party entity that assists in certain core programmatic functions. The Department believes this screening is already conducted in the routine administration and only foresees the additional cost of criminal background checks for those sponsors not already conducting such checks. In addition, the 2012 IFR requires Summer Work Travel sponsors to ensure that all participants have opportunities to interact regularly with U.S. citizens and experience U.S. culture during the work portion of their Summer Work Travel Programs and to accordingly organize events, trips, or other activities to provide them exposure to U.S. culture. The Department outlines the increased cost and burden hours associated with this collection requirement and discussed it fully in the Regulatory Flexibility Act/ Executive Order 13272: Small Business section above.

(6) You may submit comments by any of the following methods: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

(7) *The Department seeks public comment on:*

- Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- The accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information to be collected; and collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

(8) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The total number of respondents is estimated to be those 49 organizations designated by the Department to conduct the Summer Work Travel Program activities.

(9) *An estimate of the total annual public burden (in hours) associated with the collection:* The Department calculates that the new requirements under the 2012 IFR may require up to two additional hours of work per placement for Summer Work Travel sponsors that include an additional half hour for participant orientation; one additional hour towards third party screening, vetting and monitoring; and an additional half hour for the recordkeeping of the cultural component that each Summer Work Travel participant receives.

The Department estimates that for approximately half of the 109,000 annual Summer Work Travel placements, a minimal additional burden will be imposed to the sponsors given current business practices of some sponsors with respect to vetting host employers. The total burden for vetting the host employers and participant placements for all Summer Work Travel sponsors is two hours, or 218,000 hours of work, which is an increase of one hour per placement. The increased burden will be imposed on those sponsors not currently documenting host employer interviews, obtaining references and court documents, financial viability, and housing being provided.

In addition, the Department estimates that the vetting recordkeeping obligations of third party foreign agents is a standard business practice and that the total burden of a half hour per third party, should be added to the estimated half hour that it already takes to vet and establish contracts of the 960 existing foreign agents. The additional reporting of annual price lists for each foreign entity is expected to be minimal. There are approximately 960 foreign entities and the time to collect and report the price list is expected to be a half hour.

List of Subjects in 22 CFR Part 62

Cultural exchange programs, Reporting and recordkeeping requirements.

Accordingly, 22 CFR Part 62 is amended as follows:

PART 62—EXCHANGE VISITOR PROGRAM

■ 1. The authority citation for Part 62 continues to read as follows:

Authority: 8 U.S.C. 1101(a)(15)(J), 1182, 1184, 1258; 22 U.S.C. 1431–1442, 2451 *et seq.*; Foreign Affairs Reform and Restructuring Act of 1998, Pub. L. 105–277, Div. G, 112 Stat. 2681 *et seq.*; Reorganization Plan No. 2 of 1977, 3 CFR, 1977 Comp. p. 200; E.O. 12048 of March 27, 1978; 3 CFR, 1978 Comp. p. 168; the Illegal Immigration Reform and Immigrant Responsibility Act (IIRIRA) of 1996, Pub. L. 104–208, Div. C, 110 Stat. 3009–546, as amended; Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT ACT), Pub. L. 107–56, section 416, 115 Stat. 354; and the Enhanced Border

Security and Visa Entry Reform Act of 2002, Pub. L. 107–173, 116 Stat. 543.

■ 2. Section 62.32 is revised to read as follows:

§ 62.32 Summer work travel.

(a) *Introduction.* The regulations in this section (in combination with any other provisions of 22 CFR part 62, as applicable) govern participation in Summer Work Travel programs conducted by Department of State-designated sponsors pursuant to the authority granted the Department of State under Public Law 105–277.

(b) *Purpose.* The purpose of this program is to provide foreign college and university students with opportunities to interact with U.S. citizens, experience U.S. culture while sharing their own cultures with Americans they meet, travel in the United States, and work in jobs that require minimal training and are seasonal or temporary in order to earn funds to help defray a portion of their expenses. Employment is of a seasonal nature when the required service is tied to a certain time of the year by an event or pattern and requires labor levels above and beyond existing worker levels. Employment is of a temporary nature when an employer's need for the duties to be performed is a one-time occurrence, a peak load need, or an intermittent need. It is the nature of employers' needs, not the nature of the duties that is controlling.

(c) *Duration of participation.* Summer Work Travel participants are authorized to participate in the Exchange Visitor Program for up to four months during the long break between academic years as determined by the Department of State. Extensions of program participation are not permitted.

(d) *Participant screening and selection.* In addition to satisfying the requirements set forth at § 62.10(a), sponsors are solely responsible for adequately screening and making the final selection. The screening process requires that sponsors (or vetted foreign entities acting on their behalf) at a minimum must:

(1) Conduct and document interviews with potential participants either in-person or by video-conference;

(2) Verify proficiency in conversational English and reading comprehension through either recognized language tests administered by academic institutions or English language schools or through the required documented interviews;

(3) Select applicants who demonstrate their intention to participate in the cultural aspects of the Summer Work Travel Program.

(4) Confirm that at the time of application, applicants (including final year students) are enrolled full-time and pursuing studies at accredited post-secondary, classroom-based, academic institutions physically located outside of the United States and have successfully completed at least one semester, or equivalent, of post-secondary academic study.

(e) *Participant orientation.* In addition to satisfying the requirements set forth at § 62.10(b) and (c), sponsors must provide program participants, prior to participants' departures from their home countries, the following information and/or documentation:

(1) A copy of the Department of State's Summer Work Travel Participant Letter;

(2) A copy of the Department of State's Summer Work Travel Program Brochure;

(3) The Department of State's toll-free help line telephone number;

(4) The sponsor's 24/7 immediate contact telephone number;

(5) Information advising participants of their obligations to notify their sponsors within ten days after they arrive in the United States and within ten days after they initially secure or change residences;

(6) Information advising participants that they may not begin working at initial, replacement, or additional jobs until their sponsors have verified the terms and conditions of such employment and fully vetted their host employers as set forth at paragraph (n) of this section;

(7) For participants with jobs secured prior to departing from selected home countries, documentation explaining the terms and conditions of such jobs and providing information about available housing and transportation to and from work;

(8) Information explaining the cultural component of the Summer Work Travel Program, including guidance on how to best experience U.S. culture and/or descriptions of cultural opportunities arranged by the sponsor; and

(9) Information explaining that sponsors will terminate the programs of participants who fail to comply with enumerated program regulations (i.e., reporting their arrivals, reporting changes of residence, not starting work at unverified jobs, responding to sponsor monthly outreach/monitoring efforts).

(f) *Cultural exchange.* (1) Sponsors must ensure that all participants have opportunities to work alongside U.S. citizens and interact regularly with U.S. citizens to experience U.S. culture during the workday portion of their Summer Work Travel programs; and

(2) Sponsors must ensure that all participants have opportunities to engage in cultural activities or events outside of work by planning, initializing, and carrying out events or other activities that provide participants' exposure to U.S. culture.

(g) *Participant placement.* (1) Sponsors and third parties acting on their behalf may not pay or otherwise provide any incentive to employers to accept program participants for job placements with such employers.

(2) Sponsors must confirm initial, replacement, and additional jobs placements of all Summer Work Travel Program participants before participants may start work by verifying, at a minimum, the terms and conditions of such employment and fully vetting their host employers as set forth at paragraph (n) of this section. Once participants have arrived in the United States and identified initial, replacement, or additional jobs, sponsors must vet such jobs within 72 hours.

(3) Sponsors must not pose obstacles to job changes, but must offer reasonable assistance to participants wishing to change jobs regardless of whether their jobs were secured by the sponsors (direct-placed) or by the participants (self-placed).

(4) Sponsors may place participants only in jobs that:

(i) Are seasonal or temporary as defined in paragraph (b) of this section; and

(ii) Provide opportunities for regular communication and interaction with U.S. citizens and allow participants to experience U.S. culture.

(5) Sponsors may not place participants in jobs:

(i) That require licensing;

(ii) That are on the program exclusion list set forth at paragraph (h) of this section; or

(iii) For which there is another specific J visa category (e.g., Camp Counselor, Trainee, Intern).

(6) Sponsors may not place participants with staffing agencies unless the placements meet the following three criteria:

(i) Participants must be employees of and paid by the staffing agencies;

(ii) Staffing agencies must provide full-time, primary, on-site supervision of the participants;

(iii) Staffing agencies must effectively control the work sites, e.g., have hands-on management responsibility for the participants.

(7) Sponsors may not place participants with employers that fill non-seasonal or non-temporary job

openings with exchange visitors with staggered vacation schedules.

(8) Sponsors must use extra caution when placing students in positions at employers in lines of business that are frequently associated with trafficking persons (e.g., modeling agencies, housekeeping, janitorial services).

(9) Sponsors must consider the availability of suitable, affordable housing (e.g., that meets local codes and ordinances) and reliable, affordable, and convenient transportation to and from work when making job placements.

(i) If employers do not provide or arrange housing and/or transportation, or if participants decline employer-provided housing or transportation, sponsors must actively and immediately assist participants with arranging appropriate housing and transportation.

(ii) If employers provide housing and/or transportation to and from work, job offers must include details of all such arrangements, including the cost to participants; whether such arrangements deduct such costs from participants' wages; and the market value of housing and/or transportation in accordance with the Fair Labor Standards Act regulations set forth at 29 CFR part 531, if they are considered part of the compensation packages.

(10) For participants who are nationals of non-Visa Waiver Program countries and participants who are nationals of Visa Waiver Program countries with job placements screened in advance by the sponsors (direct placement) or jobs found by the participants (self-placement), prior to issuing Form DS–2019, sponsors must vet the potential employers as set forth at paragraph (n) of this section, confirm the terms and conditions of the job offers, and input complete and correct data into the Student and Exchange Visitor Information System (SEVIS) pursuant to the requirements set forth in § 62.70(f).

(11) Sponsors of applicants who are nationals of Visa Waiver Program countries and who have not secured jobs prior to departing from their home countries must:

(i) Ensure that such participants receive pre-departure information that explains how to seek employment and secure lodging in the United States, and clearly identifies the criteria for appropriate jobs set forth at paragraph (g) of this section and the categories of employment and positions that are on the program exclusion list set forth at paragraph (h) of this section;

(ii) Ensure that such participants have sufficient financial resources to support themselves during their searches for employment;

(iii) Assist participants who have not found suitable employment within one week of commencing their job searches;

(iv) Instruct participants of their obligation to notify their sponsors when they obtain job offers (and that they cannot start such jobs until the sponsors vet them); and

(v) Promptly (i.e., within 72 hours) confirm the initial jobs of such participants, at a minimum, by verifying the terms and conditions of such employment and fully vetting their host employers as set forth at paragraph (n) of this section.

(h) *Program exclusions.* Sponsors must not place participants:

(1) In positions that could bring notoriety or disrepute to the Exchange Visitor Program;

(2) In sales positions that require participants to purchase inventory that they must sell in order to support themselves;

(3) In domestic help positions in private homes (e.g., child care, elder care, gardener, chauffeur);

(4) As pedicab or rolling chair drivers or operators;

(5) As operators or drivers of vehicles or vessels for which drivers' licenses are required regardless of whether they carry passengers or not;

(6) In positions related to clinical care that involves patient contact;

(7) In any position in the adult entertainment industry (including, but not limited to jobs with escort services, adult book/video stores, and strip clubs);

(8) In positions requiring work hours that fall predominantly between 10:00 p.m. and 6:00 a.m.;

(9) In positions declared hazardous to youth by the Secretary of Labor at Subpart E of 29 CFR part 570;

(10) In positions that require sustained physical contact with other people and/or adherence to the Centers for Disease Control and Prevention's Universal Blood and Body Fluid Precautions guidelines (e.g., body piercing, tattooing, massage, manicure);

(11) In positions that are substantially commission-based and thus do not guarantee that participants will be paid minimum wage in accordance with federal and state standards;

(12) In positions involved in gaming and gambling that include direct participation in wagering and/or betting;

(13) In positions in chemical pest control, warehousing, catalogue/online order distribution centers;

(14) In positions with travelling fairs or itinerant concessionaires;

(15) In positions for which there is another specific J category (e.g., camp counselor, intern, trainee); or

(16) After November 1, 2012, in positions in the North American Industry Classification System's (NAICS) Goods-Producing Industries occupational categories industry sectors 11, 21, 23, 31–33 numbers (set forth at *http://www.bls.gov/iag/tgs/iag_index_naics.htm).*

(i) *Participant compensation.* (1) Sponsors must inform program participants of Federal, State, and Local Minimum Wage requirements, and ensure that at a minimum, participants are compensated at the higher of:

(i) The applicable Federal, State, or Local Minimum Wage (including overtime); or

(ii) Pay and benefits commensurate with those offered to their similarly situated U.S. counterparts.

(2) Sponsors must demonstrate that participants are also compensated according to the above standards in the following (and similar) situations:

(i) The host employers provide housing and/or transportation as part of participants' compensation, but the compensation package does not explain that the lower hourly wage reflects such benefits; or

(ii) The employers compensate participants on a ''piece'' basis (e.g., number of rooms cleaned). If at the end of each pay period, the participant's earnings under the piece rate do not equal at least the amount the participant would have earned had the participant been paid the predominant local wage as provided in subparagraph (1), the participant's pay must be supplemented at that time so that the participant's earnings are at least as much as the required local wage as provided in subparagraph (1).

(3) Sponsors must ensure that appropriate assistance is provided to participants on an as-needed basis and that sponsors are available to participants (and host employers) to assist as facilitators, counselors, and information resources.

(j) *Monitoring.* Sponsors must:

(1) Maintain, at a minimum, monthly personal contacts with program participants. Such contact may be in-person, by telephone, or via exchanges of electronic mail (including a response from the participant) and must be properly documented. Sponsors must promptly and appropriately address issues affecting the participants' health, safety, and welfare identified through such contacts; and

(2) Provide appropriate assistance to participants on an as-needed basis and be available to participants (and host employers) to assist as facilitators, counselors, and information resources.

(k) *Internal controls.* Sponsors must utilize organization-specific standard operating procedures for training and supervising all organization employees. In addition, sponsors must establish internal controls to ensure that employers and/or foreign entities comply with the terms of agreements with such third parties involved in the administration of the sponsors' exchange visitor programs (i.e., affect the core programmatic functions).

(l) *Sponsors' use of third parties.* (1) If sponsors utilize foreign third party entities to assist in fulfilling the core programmatic functions of screening and orientation that may be conducted outside the United States, they must first obtain written and executed agreements with such third parties. For the purpose of this section, U.S. entities operating outside the United States (or its possessions or territories) are considered foreign entities. At a minimum, these written agreements must:

(i) Outline the obligations and full relationship between the sponsors and such third parties on all matters involving the administration of the sponsors' exchange visitor programs;

(ii) Delineate the parties' respective responsibilities;

(iii) Include annually updated price lists for Summer Work Travel Programs marketed by the foreign entities including itemizations of all costs charged to participants;

(iv) Contain representations that such foreign entities will not engage in, permit the use of, or otherwise cooperate or contract with other third parties (including staffing or employment agencies or subcontractors) for the purpose of outsourcing any core programmatic functions of screening and orientation covered by the agreement; and

(v) Confirm that the foreign entities agree not to pay or provide incentives to employers in the United States to accept program participants for job placements.

(2) If sponsors utilize domestic third party entities to assist in fulfilling the core programmatic functions of orientation and promoting mutual understanding, they must first obtain written and executed agreements with such third parties. Domestic third parties engaged by sponsors may not engage or subcontract any other parties to assist in fulfilling these core programmatic functions. Only host employers may assist in providing orientation to program participants. At a minimum, these written agreements must:

(i) Outline the obligations and full relationship between the sponsors and such third parties on all matters involving the administration of the sponsors' exchange visitor programs; and

(ii) Delineate the parties' respective responsibilities.

(m) *Vetting third party foreign entities.* Sponsors must undertake appropriate due diligence in the review of potential overseas agents or partners (i.e., foreign entities) who assist in fulfilling the sponsors' core programmatic functions that may be conducted outside the United States (i.e., screening and orientation) and must, at a minimum, annually review and maintain the following documentation for potential or existing foreign entities:

(1) Proof of business licensing and/or registration to enable them to conduct business in the venue(s) where they operate;

(2) Disclosure of any previous bankruptcy and of any pending legal actions or complaints against such an entity on file with local authorities;

(3) Written references from three current business associates or partner organizations;

(4) Summary of previous experience conducting J–1 Exchange Visitor Program activities;

(5) Criminal background check reports (including original and English translations) for all owners and officers of the organizations;

(6) A copy of the sponsor-approved advertising materials the foreign entities intend to use to market the sponsors' programs (including original and English translations); and

(7) A copy of the foreign entity's notarized recent financial statements.

(n) *Vetting domestic third party entities.* Annually, sponsors must undertake appropriate due diligence in the vetting of domestic third parties who assist in the promotion of mutual understanding and potential host employers.

(1) Sponsors must ensure that third parties assisting in promoting mutual understanding (i.e., providing opportunities for participants to engage in cultural activities) are reputable individuals or organizations that are qualified to perform the activities agreed to and that they have sufficient liability insurance, if appropriate. All third parties that are registered business entities must be vetted according to the host employer procedures set forth in paragraphs (n)(2)(i) through (iii) of this section.

(2) Sponsors must ensure that potential host employers are legitimate and reputable businesses by, at a minimum:

(i) Making direct contact in person or by telephone with potential employers to verify the business owners' and/or managers' names, telephone numbers, email addresses, street addresses, and professional activities;

(ii) Utilizing publicly available information, for example, but not limited to, state registries, advertisements, brochures, Web sites, and/or feedback from prior participants to confirm that all job offers have been made by viable business entities;

(iii) Obtaining potential host employers' Employer Identification Numbers and copies of their current business licenses; and

(iv) Verifying the potential host employers' Worker's Compensation Insurance Policy or equivalent in each state where a participant will be placed or, if applicable, evidence of that state's exemption from requirement of such coverage.

(3) At the beginning of each placement season, sponsors must confirm:

(i) The number of job placements available with host employers;

(ii) That host employers will not displace domestic U.S. workers at worksites where they will place program participants; and

(iii) That host employers have not experienced layoffs in the past 120 days and do not have workers on lockout or on strike.

(o) *Host employer cooperation.* Sponsors may place participants only with host employers that agree to:

(1) Make good faith efforts to provide participants the number of hours of paid employment per week as identified on their job offers and agreed to when the sponsors vetted the jobs;

(2) Pay eligible participants for overtime worked in accordance with applicable State or Federal law;

(3) Notify sponsors promptly when participants arrive at the work sites to begin their programs; when there are any changes or deviations in the job placements during the participants' programs; when participants are not meeting the requirements of their job placements; or when participants leave their positions ahead of their planned departures;

(4) Contact sponsors immediately in the event of any emergency involving participants or any situations that impact their health, safety, or welfare; and

(5) In those instances when the employer provides housing or transportation, agree to provide suitable and acceptable accommodations and/or reliable, affordable, and convenient transportation.

(p) *Reporting requirements.* Sponsors must electronically comply with the following reporting requirements utilizing Department-provided templates:

(1) Submit placement reports on January 31 and July 31 of each year, identifying all Summer Work Travel Program participants who began exchange programs during the preceding six-month period. The reports must include the exchange visitors' names, SEVIS Identification Numbers, countries of citizenship or legal permanent residence, names of host employers, and the length of time it took non-pre-placed participants to secure job placements. For participants who change jobs or have multiple jobs during their programs, the report must include all such placements;

(2) Maintain listings of all active foreign agents or partners on the Foreign Entity Report by promptly informing the Department of any additions, deletions, or changes to foreign entity information by submitting new versions of their reports that reflect all current information. Reports must include the names, addresses, and contact information, including physical and mailing addresses, telephone numbers, and email addresses of all foreign entities that assist the sponsors in fulfilling the provision of core programmatic services. Sponsors must utilize only vetted foreign entities identified in the Foreign Entity Report to assist in fulfilling the sponsors' core programmatic functions outside the United States, and they must inform the Department promptly when and why they have cancelled contractual arrangements with foreign entities; and

(3) Submit annual participant price lists to the Department on January 31 of each year in a format approved by the Department to provide itemized breakdowns of the costs that exchange visitors must pay to both foreign agents and sponsors to participate in the Summer Work Travel Program on a country-specific (and, if appropriate, foreign agent-specific) basis.

Dated: May 4, 2012.

Robin J. Lerner,

Deputy Assistant Secretary for Private Sector Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9589]

RIN 1545–BK11

Modifications to Definition of United States Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations relating to the treatment of upfront payments made pursuant to certain notional principal contracts for U.S. federal income tax purposes. The temporary regulations provide that certain obligations of United States persons arising from upfront payments made by controlled foreign corporations pursuant to contracts that are cleared by a derivatives clearing organization or clearing agency do not constitute United States property. These regulations affect United States shareholders of controlled foreign corporations that make such payments. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking (REG–107548–11) on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date.* These regulations are effective on May 11, 2012.

Applicability Date. These regulations apply to payments described in § 1.956–2T(b)(1)(xi) made on or after May 11, 2012.

FOR FURTHER INFORMATION CONTACT: Kristine A. Crabtree at (202) 622–3840 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

A. Section 956

Section 956 was enacted to require an income inclusion by United States shareholders (as defined in section 951(b)) of a controlled foreign corporation (as defined in section 957(a)) that invests certain earnings and profits in United States property (U.S. property) ''on the grounds that [the investment] is substantially the equivalent of a dividend being paid to them.'' S. Rep. No. 87–1881, 1962–3 CB 703, 794 (1962). Under section 951(a)(1)(B), each United States shareholder (U.S. shareholder) of a controlled foreign corporation (CFC) is generally required to currently include in its gross income the amount determined under section 956 with respect to such shareholder.

The amount determined under section 956 with respect to a U.S. shareholder of a CFC for any taxable year is the lesser of: (1) The excess, if any, of the shareholder's pro rata share of the average of the amounts of U.S. property held (directly or indirectly) by the CFC as of the close of each quarter of such taxable year, over the amount of earnings and profits of the CFC described in section 959(c)(1)(A) with respect to such shareholder; or (2) the shareholder's pro rata share of the applicable earnings of the CFC. In general, the amount taken into account with respect to any U.S. property for this purpose is the adjusted basis of such property as determined for purposes of computing earnings and profits, reduced by any liability to which the property is subject. Earnings and profits described in section 959(c)(1)(A) are attributable to amounts previously included in gross income by the U.S. shareholder under section 951(a)(1)(B) (or which would have been included except for section 959(a)(2)).

Section 956(c)(1) defines U.S. property to generally include stock of a domestic corporation and an obligation of a United States person (U.S. person). Section 956(c)(2), however, generally excludes from the definition of U.S. property the stock or obligations of a domestic corporation that is neither a U.S. shareholder of the CFC nor a domestic corporation, 25 percent or more of the total combined voting power of which, immediately after the CFC's acquisition of stock in such domestic corporation, is owned, or is considered as being owned, by U.S. shareholders of the CFC. Under § 1.956–2T(d)(2), subject to certain exceptions not relevant here, the term ''obligation'' includes any bond, note, debenture, certificate, bill receivable, account receivable, note receivable, open account, or other indebtedness, whether or not issued at a discount and whether or not bearing interest.

B. NPCs With Nonperiodic (Upfront) Payments

When a notional principal contract (within the meaning of § 1.446–3(c)(1)) (NPC) includes a significant nonperiodic payment, the contract is generally treated as two separate transactions. One transaction is an on-market, level payment swap; the other is a loan. For purposes of section 956, the Commissioner may treat any nonperiodic payment in connection with an NPC, whether or not it is

significant, as one or more loans. *See* § 1.446–3(g)(4). If a party to an NPC makes below-market periodic payments or receives above-market periodic payments under the terms of the contract, typically that party will make a nonperiodic payment, such as an upfront payment, to the counterparty in order to compensate for the off-market coupon payments specified in the contract.

For example, if A and B enter into an off-market interest rate swap the terms of which require A to make periodic below-market fixed rate payments to B and require B to make periodic on-market floating rate payments to A, then A typically will compensate B (for receiving the below-market fixed rate payments) by making a nonperiodic payment at the outset of the interest rate swap (henceforth, an upfront payment) so that the present value of the fixed rate leg of the swap will equal the present value of the floating rate leg of the swap.

Recently, certain contracts (cleared contracts), including some credit default swaps and interest rate swaps, have begun to be cleared through U.S.-registered derivatives clearing organizations or clearing agencies (collectively, U.S.-registered clearinghouses). Contracts cleared through a U.S.-registered clearinghouse generally are required to have standardized terms. For example, credit default swaps that are cleared through a U.S.-registered clearinghouse have common documentation and standardized coupons (currently 100 or 500 basis points). Consequently, except for the rare instance when the market coupon rate for a particular credit default swap is exactly 100 or 500 basis points, a credit default swap with a standardized coupon will be off-market and will require an upfront payment to equalize the present value of the payment obligations under the contract.

The volume of contracts cleared by U.S.-registered clearinghouses is expected to increase substantially as a result of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Public Law 111–203, 124 Stat. 1376 (the Dodd-Frank Act). Title VII of the Dodd-Frank Act, among other things: (1) Provides for the registration and comprehensive regulation of swap dealers and major swap participants; (2) imposes clearing and trade execution requirements on many swap contracts; and (3) creates rigorous recordkeeping and real-time reporting regimes.

C. Clearinghouse Margin Requirements To Manage Credit Risk

U.S.-registered clearinghouses manage credit risk (the risk of counterparty default) in part by requiring that each party to a cleared contract provide various types of margin, including initial variation margin and daily variation margin (both of which are discussed in this section of the preamble). Cash margin payments (as well as other payments made pursuant to the terms of a cleared contract) to and from a U.S.-registered clearinghouse are made to or through a clearing member (that is, a futures commission merchant, broker, or dealer who is a member of the clearinghouse) which, in turn, makes corresponding payments to or receives corresponding payments from a counterparty.

(1) Initial Variation Margin Required To Offset Upfront Payment

The party that makes an upfront payment pursuant to a cleared contract (the first party) has credit risk with respect to that payment because, if the clearinghouse (or the first party's clearing member) were to default, the first party would not receive the full benefit it paid for (the benefit of making below-market fixed rate payments or receiving above-market payments for the term of the contract). When the U.S.-registered clearinghouse makes the upfront payment to the other party to the cleared contract (the second party), the U.S.-registered clearinghouse similarly has credit risk with respect to that second party (or its clearing member). The second party (the ultimate recipient of the upfront payment) is thus required to make a payment in the nature of variation margin (initial variation margin) to the U.S.-registered clearinghouse, generally no later than the end of the business day on which the upfront payment is made, in an amount that is equal to the upfront payment.

In some instances, the total amount of margin posted by the second party on the day that it is required to post initial variation margin may not equal the amount of the first party's upfront payment, due to either: (1) The netting of the second party's notional exposure to the first party, or to the clearinghouse, as a result of other transactions; or (2) changes in the value of the contract between the time the contract is entered into and the time when the required margin is paid, requiring daily variation margin to be added to or subtracted from the second party's initial variation margin payment, as the case may be. However, on a transaction-by-transaction basis, the payment of initial variation margin by the second party should equal the first party's upfront payment when any daily variation margin is treated as separate from the initial variation margin posted on that day.

After receiving the second party's initial variation margin payment, the U.S.-registered clearinghouse will pay the same amount to the first party. In each case, unless the first party and the second party are clearing members of the U.S.-registered clearinghouse, the payment will be made to or through each party's clearing member, which may be an affiliate of that party.

Assume that D (a dealer under section 475) and C (a customer) enter into a contract that is accepted for clearing by a U.S.-registered clearinghouse, the terms of which require D to make below-market periodic payments to C. D is required under the contract to make an upfront payment of $25,000 to compensate C for the below-market coupon payments that C will receive. D (not a clearing member) makes that upfront payment to its clearing member, who then pays the U.S.-registered clearinghouse an identical amount. The U.S.-registered clearinghouse in turn pays that amount to the clearing member for C, which makes the upfront payment to C. C, on the same business day, makes an initial variation margin payment of $25,000 to its clearing member, who then pays that amount to the U.S.-registered clearinghouse; the U.S.-registered clearinghouse makes the initial variation margin payment to D's clearing member; and D's clearing member makes the payment to D. Thus, the upfront payment from D is immediately offset by an initial variation margin payment in the same amount from C.

(2) Daily Variation Margin Required To Account for Daily Market Fluctuation

In addition to initial variation margin, U.S.-registered clearinghouses manage credit risk by requiring that each party to a cleared contract provide daily variation margin (also referred to as mark-to-market or maintenance margin). Daily variation margin is a cash margin payment made on a daily or intraday basis between the counterparties to a contract to protect against the risk of counterparty default. The rules of U.S.-registered clearinghouses generally require that daily variation margin be paid in an amount equal to the change in the fair market value of the contract.

Explanation of Provisions

The text of these temporary regulations also serves as the text of the

proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**. These temporary regulations establish an exception to the definition of U.S. property for obligations of U.S. persons arising from upfront payments made with respect to certain cleared contracts that are properly classified as NPCs. The temporary regulations provide that obligations of U.S. persons arising from such upfront payments by a CFC that is a dealer in securities or commodities (within the meaning of section 475) do not constitute U.S. property for purposes of section 956(a).

To qualify for this exception: (1) The upfront payment must be required under a contract that is cleared by a derivatives clearing organization (as such term is defined in section 1a of the Commodity Exchange Act (7 U.S.C. 1a)) or a clearing agency (as such term is defined in section 3 of the Securities Exchange Act of 1934 (15 U.S.C. 78c)) that is registered as a derivatives clearing organization under the Commodity Exchange Act or as a clearing agency under the Securities Exchange Act of 1934, respectively; (2) the CFC must make the upfront payment to or through a United States person that is a clearing member of the derivatives clearing organization or clearing agency, or directly to the derivatives clearing organization or clearing agency if the CFC is a clearing member of such derivatives clearing organization or clearing agency; (3) the upfront payment must be made, directly or indirectly, to the counterparty to the contract; (4) the counterparty to the contract must be required to make a payment in the nature of initial variation margin that is equal (before taking into account any change in the value of the contract between the time the contract is entered into and the time at which the payment is made) to the amount of the upfront payment made by the CFC; and (5) such payment in the nature of initial variation margin must be paid, directly or indirectly, to the CFC.

The IRS and the Treasury Department do not believe that an obligation of a U.S. person created by an upfront payment resulting from a cleared contract that satisfies the requirements listed in this regulation is the type of transaction intended to be covered by section 956, whether or not the payment is treated as a loan under the NPC rules under section 446. While the section 956 exception in these temporary regulations currently is limited to cleared contracts, the IRS and the Treasury Department continue to study, and request comments on, whether and under what circumstances it would be appropriate to extend the exception to contracts that are not cleared by a U.S.-registered clearinghouse, but that would otherwise meet the criteria set forth in these temporary regulations.

Effective/Applicability Date

These regulations apply to payments described in § 1.956–2T(b)(1)(xi) made on or after May 11, 2012. However, taxpayers may apply the rules of these regulations retroactively to payments made prior to May 11, 2012.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), refer to the cross-reference notice of proposed rulemaking published in the proposed rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small entities.

Drafting Information

The principal author of these regulations is Kristine A. Crabtree of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *
Section 1.956–2T(b)(1)(xi) also issued under 26 U.S.C. 956(e). * * *

■ **Par. 2.** Section 1.956–2 is amended by adding a new paragraph (b)(1)(xi) to read as follows:

§ 1.956–2 Definition of United States property.

* * * * *

(b) * * *
(1) * * *
(xi) [Reserved]. For further guidance, see § 1.956–2T(b)(1)(xi).

* * * * *

■ **Par. 3.** Section 1.956–2T is amended by:
■ 1. Revising paragraphs (a) through (d)(1).
■ 2. Adding new paragraphs (f) and (g).
The revisions and additions read as follows:

§ 1.956–2T Definition of United States property (temporary).

(a) through (b)(1)(x) [Reserved]. For further guidance, see § 1.956–2(a) through (b)(1)(x).

(xi) An obligation of a United States person arising from an upfront payment by a controlled foreign corporation (within the meaning of section 957(a)) with respect to a notional principal contract (within the meaning of § 1.446–3(c)(1)) where the following conditions are satisfied—

(A) The controlled foreign corporation that makes the upfront payment is a dealer in securities or commodities (within the meaning of section 475(c)(1) or (e)(1));

(B) The upfront payment is required under a contract that is cleared by a derivatives clearing organization (as such term is defined in section 1a of the Commodity Exchange Act (7 U.S.C. 1a)) or a clearing agency (as such term is defined in section 3 of the Securities Exchange Act of 1934 (15 U.S.C. 78c)) that is registered as a derivatives clearing organization under the Commodity Exchange Act or as a clearing agency under the Securities Exchange Act of 1934, respectively;

(C) The controlled foreign corporation makes the upfront payment:

(*1*) To or through a United States person that is a clearing member of a derivatives clearing organization or clearing agency, or

(*2*) Directly to the derivatives clearing organization or clearing agency if the controlled foreign corporation is a clearing member of such derivatives clearing organization or clearing agency;

(D) The upfront payment is made by the derivatives clearing organization or clearing agency, directly or indirectly, to the original counterparty to the contract;

(E) The original counterparty to the contract that receives the upfront payment, as described in paragraph (b)(1)(xi)(D) of this section, is required by the derivatives clearing organization or clearing agency to make, by the end of the business day on which the upfront payment is made by the controlled foreign corporation, a payment in the nature of initial

variation margin that is equal (before taking into account any change in the value of the contract between the time the contract is entered into and the time at which the payment is made) to the amount of the upfront payment and such payment is made, directly or indirectly, to the derivatives clearing organization or clearing agency; and

(F) The payment in the nature of initial variation margin is paid by the derivatives clearing organization or clearing agency, directly or indirectly, to the controlled foreign corporation.

(G) *Examples.* The following examples illustrate the application of this paragraph (b)(1)(xi):

Example 1. CFC is a controlled foreign corporation that is wholly owned by USP, a domestic corporation. CFC is a dealer in securities under section 475(c)(1). CFC enters into a credit default swap (that it treats as a notional principal contract for U.S. federal income tax purposes) with unrelated counterparty B. The credit default swap is accepted for clearing by a U.S.-registered derivatives clearing organization (DCO). CFC is not a member of DCO. CFC uses a U.S. affiliate (CM), which is a member of DCO, as its clearing member to submit the credit default swap to be cleared. CM is a domestic corporation that is wholly owned by USP. The standardized terms of the credit default swap provide that, for a term of X years, CFC will pay B a fixed coupon of 100 basis points per year on a notional amount of $Y. At the time CFC and B enter into the credit default swap, the market coupon for similar credit default swaps is 175 basis points per year. To compensate B for the below-market annual coupon payments that B will receive, the contract requires CFC to make an upfront payment through CM to DCO. DCO then makes the upfront payment to B through B's clearing member. DCO also requires B to post initial variation margin in an amount equal to the upfront payment. B pays the initial variation margin through its clearing member to DCO. DCO then pays the initial variation margin through CM to CFC. Because the conditions set out in this paragraph (b)(1)(xi) are satisfied, the obligation of CM arising from the upfront payment by CFC does not constitute United States property for purposes of section 956.

Example 2. Assume the same facts as in *Example 1,* except that counterparty B is, like CM, a domestic corporation that is wholly owned by USP. Because the conditions set out in this paragraph (b)(1)(xi) are satisfied, the obligations of CM and B arising from the upfront payment by CFC do not constitute United States property for purposes of section 956.

Example 3. Assume the same facts as in *Example 2,* except that CFC uses an unrelated person as its clearing member. Because the conditions set out in this paragraph (b)(1)(xi) are satisfied, the obligation of B arising from the upfront payment by CFC does not constitute United States property for purposes of section 956.

(b)(2) through (d)(1) [Reserved]. For further guidance, see § 1.956–2(b)(2) through (d)(1).

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(f) *Effective/applicability date.* Paragraph (b)(1)(xi) applies to payments described in § 1.956–2T(b)(1)(xi) made on or after May 11, 2012. Taxpayers may apply the rules of paragraph (b)(1)(xi) to payments described in § 1.956–2T(b)(1)(xi) made prior to May 11, 2012.

(g) *Expiration date.* The applicability of paragraph (b)(1)(xi) expires on Friday, May 8, 2015.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: May 1, 2012.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2012–11329 Filed 5–10–12; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 236

[DOD–2009–OS–0183/RIN 0790–AI60]

Department of Defense (DoD)-Defense Industrial Base (DIB) Voluntary Cyber Security and Information Assurance (CS/IA) Activities

AGENCY: Office of the DoD Chief Information Officer, DoD.

ACTION: Interim final rule.

SUMMARY: DoD is publishing an interim final rule to establish a voluntary cyber security information sharing program between DoD and eligible DIB companies. The program enhances and supplements DIB participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems.

DATES: This rule is effective May 11, 2012. Comments must be received by July 10, 2012.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: DIB Cyber Security and Information Assurance Program Office: (703) 604–3167, toll free (855) 363–4227, email *DIB.CS/IA.Reg@osd.mil.*

SUPPLEMENTARY INFORMATION:

Background

Cyber threats to DIB unclassified information systems represent an unacceptable risk of compromise of DoD information and pose an imminent threat to U.S. national security and economic security interests. DoD's voluntary DIB CS/IA program enhances and supplements DIB participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems.

This rule is being published as an interim final rule to:

(a) Allow eligible DIB companies to receive USG threat information and share information about network intrusions that could compromise critical DOD programs and missions.

(b) Permit DIB companies and DOD to assess and reduce damage to critical DOD programs and missions when DOD information is compromised.

(c) Fulfill statutory requirements to ensure the protection of DOD information.

(d) Address vigorous congressional and public interest in increasing cyber security and information assurance activities through government-industry cooperation.

(e) Immediately provide a voluntary framework for DOD and DIB companies to share information to address sophisticated cyber threats that represent an imminent threat to U.S. national security and economic security interests.

Until this rule is published as an interim final rule, eligible DIB companies cannot receive USG information about cyber threats and mitigation strategies or share information about cyber incidents that may compromise critical DOD programs and missions. Without this information, eligible DIB companies' ability to protect USG information cannot be fully effective. While this vulnerability remains open, the USG faces an elevated risk that critical program information

could be compromised, resulting in potential economic losses or damage to U.S. national security. For example, the compromise of such information can significantly diminish return on DIB company and U.S. Government research and development investment and represents a loss of intellectual property that compromises the security and technical advantages of DoD weapons systems.

DIB CS/IA activities, including the collection, management and sharing of information for cyber security purposes, support and implement the following national and DoD-specific guidance and authority: information assurance (IA) requirements to establish programs and activities to protect DoD information and DoD information systems, including information and information systems operated and maintained by contractors or others in support of DoD activities (see 10 U.S.C. 2224; and the Federal Information Security Management Act (FISMA), codified at 44 U.S.C. 3541 et seq.); critical infrastructure protection responsibilities, in which DoD is the sector specific agency for the DIB sector, (see Homeland Security Presidential Directive 7 (HSPD–7), ''Critical Infrastructure Identification, Prioritization, and Protection'').

The DoD established the voluntary DIB CS/IA program to enhance and supplement DIB participants' capabilities to safeguard DoD unclassified information that resides on, or transits, DIB unclassified information systems. At the core of the program is a bilateral cyber security information sharing activity, in which DoD provides cyber threat information and information assurance (IA) best practices to DIB companies to enhance and supplement DIB companies' capabilities to safeguard DoD unclassified information; and in return, DIB companies report certain types of cyber intrusion incidents to the Defense Cyber Crime Center's DoD-DIB Collaborative Information Sharing Environment (DCISE), DoD's operational focal point for cyber threat information sharing and incident response under this program. The DoD analyzes the information reported by the DIB company regarding any such cyber incident, to glean information regarding cyber threats, vulnerabilities, and the development of effective response measures. In addition to this initial reporting and analysis, the DoD and DIB company may pursue, on a voluntary basis, follow-on, more detailed, digital forensics analysis or damage assessments of individual incidents, including sharing of additional electronic media/files or information regarding the incident or the affected systems, networks, or information. The information sharing arrangements between the DoD and each participating DIB company are memorialized in a standardized bilateral Framework Agreement (FA), signed by the participating DIB company and the Government, that implements the requirements of this part and is signed by the participating DIB company and the Government. The FA is available to eligible DIB companies during the application process. As provided by the FA, participation in the program is entirely voluntary and does not obligate any DIB participant to change its information systems or otherwise alter its normal conduct of cyber security activities. In keeping with the voluntary, collaborative nature of the activity described in the FA, each Party bears responsibility for its own actions under this FA. The FA emphasizes sharing to the greatest extent possible information to provide the clearest understanding of the cyber threat. This will allow the Company to improve defense and remediation efforts and allow the Government to assess the damage or impact to defense information and programs entrusted to the Company.

A foundational element of this bilateral information sharing model is the recognition that the information being shared between the parties includes extremely sensitive nonpublic information, which must be protected against unauthorized uses and disclosures in order to preserve the integrity of the program. For example, the cyber threat information shared by the Government must be protected against compromise by the cyber threat, which may already have a presence on the DIB participant's system; and thus the DIB participants must utilize security measures and limited sharing within the company, to ensure that the cyber threat information retains its operational value—for the benefit of all of the DIB participants. Similarly, the DIB participants typically treat information regarding potential cyber intrusion incidents on their networks as extremely sensitive proprietary, commercial, or operational information and tightly control that information within the company, let alone sharing outside the company. The DIB participants share this type of information with the Government only on the condition that the Government safeguards that information against any unauthorized use or release (both within the Government and outside the Government), which could cause substantial competitive harm to the DIB participant that reported that information. In addition, during any follow-on forensics or damage assessment activities, the Government and DIB companies may share additional types of sensitive information, which may include information regarding the types of DoD information or DIB company information that may have been compromised during the reported incident—potentially including the most sensitive types of unclassified information (e.g., critical program information relating to DoD weapons systems, DIB company trade secrets related to DoD programs, personally identifiable information (PII) regarding individuals). For additional information regarding the Government's safeguarding of information received from the DIB companies, with specific focus on PII, see the Privacy Impact Assessment for the DIB CS/IA Program (*http://dodcio.defense.gov/Portals/0/Documents/DIB%20CS-IA%20PIA_FINAL_signed_30jun2011_VMSS_GGMR_RC.pdf*).

As part of DoD's instantiation of the voluntary DIB CS/IA program, DoD developed new policies and procedures, developed a dedicated threat sharing and collaboration system, and validated on-line application procedures in order to support participation by a large number of companies. The on-line application procedures provide the administrative and security requirements for DIB participants, including the standardized bilateral FA that implements the requirements of the DIB CS/IA program. The FA will typically be executed by a senior DoD official, such as the DoD Chief Information Officer (CIO), and by a DIB company corporate senior official (e.g., Company CIO or equivalent).

This interim-final rule establishes a new part 236 in title 32 of the Code of Federal Regulations, with the following new sections: Section 236.2 establishes the definitions of terms used in the new part, leveraging established definitions to the maximum extent possible (e.g., those provided in the Committee on National Security Systems Instruction No. 4009, ''National Information Assurance Glossary'') (*http://www.cnss.gov/Assets/pdf/cnssi_4009.pdf*); Section 236.4 sets forth the basic requirements and procedures of the voluntary program, including information collection requirements; Section 236.5 characterizes cyber security information sharing and collection procedures; Section 236.6 establishes the general provisions of the voluntary DIB CS/IA program; and Section 236.7 sets forth the eligibility

requirements to participate in the voluntary program.

Nothing in this rule or program is intended to be inconsistent with any other related or similar federal agency or private sector activity or requirement. For example, nothing in this rule or program abrogates the Government's or the DIB participants' rights or obligations regarding the handling, safeguarding, sharing, or reporting of information, or regarding any physical, personnel, or other security requirements, as required by law, regulation, policy, or a valid legal contractual obligation.

Similarly, this rule and program are intended to be consistent and coordinated with, and updated as necessary to ensure consistency with and support for, other federal activities related to the handling and safeguarding of controlled unclassified information, such as those that are being led by the National Archives and Records Administration pursuant to Executive Order 13556 ''Controlled Unclassified Information'' (November 4, 2010) (see *http://www.archives.gov/cui/*).

Executive Orders 12866, ''Regulatory Planning and Review'' and 13563, ''Improving Regulation and Regulatory Review''

It has been certified that 32 CFR part 236 does not:

(a) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way, the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(b) Create a serious inconsistency, or otherwise interfere with, an action taken or planned by another Agency;

(c) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(d) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles as set forth in these Executive Orders.

Public Law 104–121, ''Congressional Review Act'' (5 U.S.C. 801)

It has been determined that 32 CFR part 236 is not a ''major'' rule under 5 U.S.C. 801, enacted by Public Law 104–121, because it will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

It has been certified that 32 CFR part 236 does not contain a Federal mandate that may result in expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

It has been certified that 32 CFR part 236 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. DIB participation in the DIB CS/IA Program is voluntary.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

Sections 236.4 and 236.5 and 236.7 of this interim final rule contain information collection requirements. DoD has submitted the following proposal to Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

(a) *Title: Defense Industrial Base Cyber Security/Information Assurance (DIB CS/IA) Points of Contact Information.*

Type of Request: New.

Projected Responses per Respondent: One response is required initially and thereafter only on an ''as needed/required'' basis, as changes to the points of contact occur.

Annual Responses: 275, which includes the additional responses required on an ''as needed/required'' basis.

Average Burden per Response: 20 minutes.

Annual Burden Hours: Total annual burden for respondents 92 hours.

Total Annualized Cost to Respondents: One-time cost of ~$12 per respondent. Total cumulative annual cost for 250 respondents (275 responses) is $3,337.

Needs and Uses: The DIB CS/IA program collects Point of Contact (POC) information from DIB participants. POC information is needed to facilitate communication between DoD and DIB participants, as well as prospective participants. The POC information includes the names, security clearance information, citizenship, work addresses, including division/group, work email addresses and work telephone numbers of company-identified representatives. DIB POCs include the Chief Executive Officer (CEO), Chief Information Officer (CIO), Chief Information Security Officer (CISO), General Counsel, the Chief Privacy Officer, and the Corporate Security Officer (CSO) or Facility Security Officer (FSO), or their equivalents. DIB participants also provide POC information for personnel responsible for the implementation and execution of the DIB CS/IA program within their company including designated personnel authorized to report incidents and any policy, administrative, or technical personnel identified to interact with DOD in the operational implementation of the program.

Affected Public: Business or other for-profit and not-for-profit institutions participating in the voluntary DIB CS/IA program.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

(b) *Title: DIB Cyber Security/Information Assurance Cyber Incident Reporting.*

Type of Request: New.

Phased expansion of DIB CS/IA Number of Participants increases to 750 over three years.

Projected Responses per Participant: 5.

Annual Responses: Year 1 responses are 1,250. Year 2 responses are 2,500. Year 3 responses are 3,750.

Average Burden per Response: 7 hours (this includes searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information).

Annual Burden Hours: Year 1 burden hours are 8,750 hours. Year 2 burden hours are 17,500 hours. Year 3 burden hours are 26,250 hours.

Needs and Uses: The collection of this information is necessary to enhance and supplement DIB participants' information security capabilities to safeguard DoD information that resides on, or transits, DIB unclassified

information systems. The requested information supports the information assurance objectives, cyber threat information sharing, and incident reporting between DoD and the DIB participants. In most cases, DIB participants report incidents using a DIB CS/IA standardized Incident Collection Form (ICF). In some cases, a company may elect to report the incident without using the ICF; and companies may report incidents through a variety of communications channels, including email, fax, or by phone, if necessary.

Affected Public: Business or other for-profit and not-for-profit institutions participating in the DIB CS/IA program.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Written comments and recommendations on the information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, DoD Desk Officer, Room 10102, New Executive Office Building, Washington, DC 20503, with a copy to the Director, DIB CS/IA Program Office, at the Office of the DoD Chief Information Officer, 6000 Defense Pentagon, Attn: DIB CS/IA Program Office, Washington, DC 20301, or email at *DIB.CS/IA.Reg@osd.mil.* Comments can be received from 30 to 60 days after the date of this notice, but comments to OMB will be most useful if received by OMB within 30 days after the date of this notice.

You may also submit comments, identified by docket number and title, by the following method: *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

To request more information on this information collection or to obtain a copy of the proposal and associated collection instruments, please write to Director, DIB CS/IA Program Office, at Office of the DoD Chief Information Officer, Attn: DIB CS/IA Program Office, 6000 Defense Pentagon, Washington, DC 20301.

Executive Order 13132, ''Federalism''

It has been certified that 32 CFR part 236 does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

(a) The States;

(b) The relationship between the National Government and the States; or

(c) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 236

Contracts, Security measures.

Accordingly 32 CFR part 236 is added to read as follows:

PART 236—DEPARTMENT OF DEFENSE (DOD)-DEFENSE INDUSTRIAL BASE (DIB) VOLUNTARY CYBER SECURITY AND INFORMATION ASSURANCE (CS/IA) ACTIVITIES

Sec.
236.1 Purpose.
236.2 Definitions.
236.3 Policy.
236.4 Procedures.
236.5 Cyber security information sharing.
236.6 General provisions.
236.7 DIB participant eligibility requirements.

Authority: 10 U.S.C. 2224; 44 U.S.C. 3506; 44 U.S.C. 3544.

§ 236.1 Purpose.

Cyber threats to DIB unclassified information systems represent an unacceptable risk of compromise of DoD information and pose an imminent threat to U.S. national security and economic security interests. DoD's voluntary DIB CS/IA program enhances and supplements DIB participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems.

§ 236.2 Definitions.

As used in this part:

(a) *Attribution information* means information that identifies the DIB participant, whether directly or indirectly, by the grouping of information that can be traced back to the DIB participant (e.g., program description, facility locations).

(b) *Compromise* means disclosure of information to unauthorized persons or a violation of the security policy of a system in which unauthorized intentional, or unintentional, disclosure, modification, destruction, loss of an object, or the copying of information to unauthorized media may have occurred.

(c) *Covered defense information* means unclassified information that:

(1) Is:

(i) Provided by or on behalf of the DoD to the DIB participant in connection with an official DoD activity; or

(ii) Collected, developed, received, transmitted, used, or stored by the DIB participant in support of an official DoD activity; and

(2) Is:

(i) Technical information marked for restricted distribution in accordance with DoD Directive 5230.25, ''Withholding of Unclassified Technical Data From Public Disclosure,'' or DoD Directive 5230.24, ''Distribution Statements on Technical Documents'';

(ii) Information subject to export control under the International Traffic in Arms Regulations (ITAR) (*http://pmddtc.state.gov/regulations_laws/itar_official.html*), or the Export Administration Regulations (EAR) (*http://ecfr.gpoaccess.gov,* Title 15, part 730);

(iii) Information designated as Critical Program Information (CPI) in accordance with DoD Instruction 5200.39, ''Critical Program Information (CPI) Protection within the Department of Defense'';

(iv) Information that hostile intelligence systems might obtain that could be interpreted or pieced together to derive critical intelligence in time to be useful to adversaries as described in 5205.02–M, ''DoD Operations Security (OPSEC Program Manual'';

(v) Personally Identifiable Information (PII) that can be used to distinguish or trace an individual's identity in accordance with DoD Directive 5400.11, ''DoD Privacy Program'';

(vi) Information bearing current and prior designations indicating unclassified controlled information (e.g., For Official Use Only, Sensitive But Unclassified, and Limited Official Use, DoD Unclassfied Controlled Nuclear Information, Sensitive Information) that has not been cleared for public release in accordance with DoD Directive 5230.29, ''Clearance of DoD Information for Public Release'' (see also Appendix 3 of DoD 5200.1–R, ''Information Security Program Regulation''); or

(vii) Any other information that is exempt from mandatory public disclosure under DoD Directive 5400.07, ''DoD Freedom of Information Act (FOIA) Program'', and DoD Regulation 5400.7–R, ''DoD Freedom of Information Program''.

(d) *Covered DIB systems* means an information system that is owned or operated by or for a DIB participant and that processes, stores, or transmits covered defense information.

(e) *Cyber incident* means actions taken through the use of computer networks that result in an actual or potentially adverse effect on an information system and/or the information residing therein.

(f) *Cyber intrusion damage assessment* means a managed, coordinated process to determine the effect on defense programs, defense scientific and research projects, or defense warfighting capabilities resulting from compromise of a DIB participant's unclassified computer system or network.

(g) *Defense Industrial Base (DIB)* means the Department of Defense, government, and private sector worldwide industrial complex with capabilities to perform research and development, design, produce, and maintain military weapon systems, subsystems, components, or parts to satisfy military requirements.

(h) *DIB participant* means a DIB company that has met all of the eligibility requirements to participate in the voluntary DIB CS/IA information sharing program as set forth in this part (see § 236.7).

(i) Government means the United States Government.

(j) *Government Furnished Information (GFI)* means information provided by the Government under the voluntary DIB CS/IA program, including but not limited to cyber threat information and information assurance practices.

(k) *Information* means any communication or representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual.

(l) *Information system* means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

(m) *Threat* means any circumstance or event with the potential to adversely impact organization operations (including mission, functions, image, or reputation), organization assets, individuals, other organizations, or the Nation through an information system via unauthorized access, destruction, disclosure, modification of information and/or denial of service.

§ 236.3 Policy.

It is DoD policy to:

(a) Establish a comprehensive approach for enhancing and supplementing DIB information assurance capabilities to safeguard covered defense information on covered DIB systems.

(b) Increase the Government and DIB situational awareness of the extent and severity of cyber threats to DOD information.

§ 236.4 Procedures.

(a) The Government and each DIB participant will execute a voluntary standardized agreement, referred to as a Framework Agreement (FA), to share, in a timely and secure manner, on a recurring basis, and to the greatest extent possible, cyber security information relating to information assurance for covered defense information on covered DIB systems.

(b) Each such FA between the Government and a DIB participant must comply with and implement the requirements of this part, and will include additional terms and conditions as necessary to effectively implement the voluntary information sharing activities described in this part with individual DIB participants.

(c) DoD's DIB CS/IA Program Office is the overall point of contact for the program. The DoD Cyber Crime Center's DoD-DIB Collaborative Information Sharing Environment (DC3/DCISE) is the operational focal point for cyber threat information sharing and incident reporting under the DIB CS/IA program.

(d) The Government will maintain a Web site or other Internet-based capability to provide potential DIB participants with information about eligibility and participation in the program, to enable the online application or registration for participation, and to support the execution of necessary agreements with the Government. (*http://dibnet.dod.mil/*)

(e) Prior to receiving GFI from the Government, each DIB participant shall provide the requisite points of contact information, to include security clearance and citizenship information, for the designated personnel within their company (e.g., typically 3–10 company designated points of contact) in order to facilitate the DoD-DIB interaction in the DIB CS/IA program. The Government will confirm the accuracy of the information provided as a condition of that point of contact being authorized to act on behalf of the DIB participant for this program.

(f) GFI will be issued via both unclassified and classified means. DIB participant handling and safeguarding of classified information shall be in compliance with the National Industrial Security Program Operating Manual (NISPOM) (DoD 5220.22–M). The Government shall specify transmission and distribution procedures for all GFI, and shall inform DIB participants of any revisions to previously specified transmission or procedures.

(g) Except as authorized in this part or in writing by the Government, DIB participants may use GFI to safeguard covered defense information only on covered DIB systems that are U.S. based (i.e., provisioned, maintained, or operated within the physical boundaries of the United States); and share GFI only within their company or organization, on a need to know basis, with distribution restricted to U.S. citizens (i.e., a person born in the United States, or naturalized, holding a U.S. passport). However, in individual cases, upon request of a DIB participant that has determined that it requires the ability to share the information with a non-U.S. citizen, or to use the GFI on a non-U.S. based covered DIB system, and can demonstrate that appropriate information handling and protection mechanisms are in place, the Government may authorize such disclosure or use under appropriate terms and conditions.

(h) DIB participants shall maintain the capability to electronically disseminate GFI within the Company in an encrypted fashion (e.g., using Secure/Multipurpose Internet Mail Extensions (S/MIME), secure socket layer (SSL), Transport Layer Security (TLS) protocol version 1.2, DoD-approved medium assurance certificates).

(i) The DIB participants shall not share GFI outside of their company or organization, regardless of personnel clearance level, except as authorized in this part or otherwise authorized in writing by the Government.

(j) If the DIB participant utilizes a third-party service provider (SP) for information system security services, the DIB participant may share GFI with that SP under the following conditions and as authorized in writing by the Government:

(1) The DIB participant must identify the SP to the Government and request permission to share or disclose any GFI with that SP (which may include a request that the Government share information directly with the SP on behalf of the DIB participant) solely for the authorized purposes of this program;

(2) The SP must provide the Government with sufficient information to enable the Government to determine whether the SP is eligible to receive such information, and possesses the capability to provide appropriate protections for the GFI;

(3) Upon approval by the Government, the SP must enter into a legally binding agreement with the DIB participant (and also an appropriate agreement with the Government in any case in which the SP will receive or share information directly with the Government on behalf of the DIB participant) under which the SP is subject to all applicable requirements of

this part and of any supplemental terms and conditions in the DIB participant's FA with the Government, and which authorizes the SP to use the GFI only as authorized by the Government.

(k) The DIB participant may not sell, lease, license, or otherwise incorporate the GFI into its products or services, except that this does not prohibit a DIB participant from being appropriately designated an SP in accordance with paragraph (j) of this section.

§ 236.5 Cyber security information sharing.

(a) *GFI.* The Government shall share GFI with DIB participants or designated SPs in accordance with this part.

(b) *Initial incident reporting.* The DIB participant shall report to DC3/DCISE cyber incidents involving covered defense information on a covered DIB system. These initial reports will be provided within 72 hours of discovery. DIB participants also may report other cyber incidents to the Government if the DIB participant determines the incident may be relevant to information assurance for covered defense information or covered DIB systems or other information assurance activities of the Government.

(c) *Follow-up reporting.* After an initial incident report, the Government and the DIB participant may voluntarily share additional information that is determined to be relevant to a reported incident, including information regarding forensic analyses, mitigation and remediation, and cyber intrusion damage assessments.

(d) *Cyber intrusion damage assessment.* Following analysis of a cyber incident, DC3/DCISE may provide information relevant to the potential or known compromise of DoD acquisition program information to the Office of the Secretary of Defense's Damage Assessment Management Office (OSD DAMO) for a cyber intrusion damage assessment. The Government may provide DIB participants with information regarding the damage assessment.

(e) *DIB participant attribution information.* The Government acknowledges that information shared by the DIB participants under this program may include extremely sensitive proprietary, commercial, or operational information that is not customarily shared outside of the company, and that the unauthorized use or disclosure of such information could cause substantial competitive harm to the DIB participant that reported that information. The Government shall take reasonable steps to protect against the unauthorized use or release of such information (e.g., attribution information and other nonpublic information) received from a DIB participant or derived from such information provided by a DIB participant, including applicable procedures pursuant to paragraph (h) of this section. The Government will restrict its internal use and disclosure of attribution information to only Government personnel and Government support contractors that are bound by appropriate confidentiality obligations and restrictions relating to the handling of this sensitive information and are engaged in lawfully authorized activities.

(f) *Non-attribution information.* The Government may share non-attribution information that was provided by a DIB participant (or derived from information provided by a DIB participant) with other DIB participants in the DIB CS/IA program, and may share such information throughout the Government (including with Government support contractors that are bound by appropriate confidentiality obligations) for cyber security and information assurance purposes for the protection of Government information or information systems.

(g) *Electronic media.* Electronic media/files provided by DIB participants to DC3 under paragraphs (b), (c) and (d) of this section are maintained by the digital and multimedia forensics laboratory at DC3, which implements specialized handling procedures to maintain its accreditation as a digital and multimedia forensics laboratory. DC3 will maintain, control, and dispose of all electronic media/files provided by DIB participants to DC3 in accordance with established DoD policies and procedures.

(h) *Freedom of Information Act (FOIA).* Agency records, which may include qualifying information received from non-federal entities, are subject to request under the Freedom of Information Act (5 U.S.C. 552) (FOIA), which is implemented in the Department of Defense by DoD Directive 5400.07 and DoD Regulation 5400.7–R (see 32 CFR parts 285 and 286, respectively). Pursuant to established procedures and applicable regulations, the Government will protect sensitive nonpublic information under this Program against unauthorized public disclosure by asserting applicable FOIA exemptions, and will inform the non-Government source or submitter (e.g., DIB participants) of any such information that may be subject to release in response to a FOIA request, to permit the source or submitter to support the withholding of such information or pursue any other available legal remedies.

§ 236.6 General provisions.

(a) Confidentiality of information that is exchanged under this program will be protected to the maximum extent authorized by law, regulation, and policy.

(b) The Government and DIB participants will conduct their respective activities under this program in accordance with applicable laws and regulations, including restrictions on the interception, monitoring, access, use, and disclosure of electronic communications or data. The Government and the DIB participant each bear responsibility for their own actions under this program.

(c) Prior to sharing any information with the Government under this program pursuant to the FA, the DIB participant shall perform a legal review of its policies and practices that support its activities under this program, and shall make a determination that such policies, practices, and activities comply with applicable legal requirements. The Government may request from any DIB participant additional information or assurances regarding such DIB participant's policies or practices, or the determination by the DIB participant that such policies or practices comply with applicable legal requirements.

(d) This voluntary DIB CS/IA program is intended to safeguard covered defense information. None of the restrictions on the Government's use or sharing of information under the DIB CS/IA program shall limit the Government's ability to conduct law enforcement, counterintelligence activities, or other activities in the interest of national security; and participation does not supersede other regulatory or statutory requirements.

(e) Participation in the DIB CS/IA program is voluntary and does not obligate the DIB participant to utilize the GFI in, or otherwise to implement any changes to, its information systems. Any action taken by the DIB participant based on the GFI or other participation in this program is taken on the DIB participant's own volition and at its own risk and expense.

(f) A DIB participant's voluntary participation in this program is not intended to create any unfair competitive advantage or disadvantage in DoD source selections or competitions, or to provide any other form of unfair preferential treatment, and shall not in any way be represented or interpreted as a Government endorsement or approval of the DIB

participant, its information systems, or its products or services.

(g) The DIB participant and the Government may each unilaterally limit or discontinue participation in this program at any time. Termination shall not relieve the DIB participant or the Government from obligations to continue to protect against the unauthorized use or disclosure of GFI, attribution information, contractor proprietary information, third-party proprietary information, or any other information exchanged under this program, as required by law, regulation, contract, or the FA.

(h) Upon termination of the FA, and/or change of Facility Security Clearance status below Secret, GFI must be returned to the Government or destroyed pursuant to direction of, and at the discretion of, the Government.

(i) Participation in this program does not abrogate the Government's or the DIB participants' rights or obligations regarding the handling, safeguarding, sharing, or reporting of information, or regarding any physical, personnel, or other security requirements, as required by law, regulation, policy, or a valid legal contractual obligation.

§ 236.7 DIB participant eligibility requirements.

To be eligible to participate in this program, a DIB company must:

(a) Have or acquire DoD-approved medium assurance certificates to enable encrypted unclassified information sharing between the Government and DIB participants;

(b) Have an existing active Facility Security Clearance (FCL) granted under the National Industrial Security Program Operating Manual (NISPOM) (DoD 5220.22–M) with approved safeguarding for at least Secret information, and continue to qualify under the NISPOM for retention of its FCL and approved safeguarding (*http://www.dtic.mil/whs/directives/corres/pdf/522022m.pdf*);

(c) Have or acquire a Communication Security (COMSEC) account in accordance with the NISPOM Chapter 9, Section 4 (DoD 5220.22–M), which provides procedures and requirements for COMSEC activities;

(d) Obtain access to DoD's secure voice and data transmission systems supporting the DIB CS/IA program,

(e) Own or operate covered DIB system(s), and

(f) Execute the standardized FA with the Government (available during the application process), which implements the requirements set forth in sections 236.4 through 236.6 of this part.

Dated: April 30, 2012.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–10651 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2012–0123]

RIN 1625–AA08, 1625–AA00

Special Local Regulations and Safety Zone; War of 1812 Bicentennial Commemorations, Chesapeake Bay and Port of Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations and a safety zone in the Chesapeake Bay and Port of Baltimore, Maryland for War of 1812 Bicentennial Commemorations activities. These actions are necessary to provide for the safety of life on navigable waters before, during, and after War of 1812 Bicentennial Commemorations events being planned for Baltimore, Maryland. These actions will restrict vessel traffic in portions of the Inner Harbor, the Northwest Harbor, the Patapsco River, and the Chesapeake Bay.

DATES: This rule is effective from June 12, 2012 through June 20, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2012–0123 and are available online by going to *http://www.regulations.gov,* inserting USCG–2012–0123 in the ''Keyword'' box, and then clicking ''Search.'' This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Mr. Ronald Houck, U.S. Coast Guard Sector Baltimore, MD; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On March 15, 2012, we published a notice of proposed rulemaking (NPRM) entitled ''War of 1812 Bicentennial Commemorations, Chesapeake Bay and Port of Baltimore, MD'' in the **Federal Register** (77 FR 15323). We received one comment on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The U.S. Department of the Navy is sponsoring War of 1812 Bicentennial Commemorations in the Chesapeake Bay and Port of Baltimore, Maryland. Planned events include the scheduled arrival of U.S. and foreign naval vessels, public vessels, tall ships and other vessels beginning on June 12, 2012 and the scheduled departure of those vessels ending on June 20, 2012. The Coast Guard anticipates a large spectator fleet for these events. Operators should expect significant vessel congestion along the arrival and departure routes. The purpose of these regulations is to promote maritime safety and protect participants and the boating public in the Port of Baltimore and the waters of the Chesapeake Bay immediately prior to, during, and after the scheduled events. The regulations will provide for clear passage of participating vessels, a safety buffer around the participating vessels while they are in transit for the benefit of participants and spectators. The regulations will impact the movement of all vessels operating in specified waters of the Chesapeake Bay, Patapsco River, Northwest Harbor and the Inner Harbor.

It may be necessary for the Coast Guard to establish additional safety or security zones in addition to these regulations to safeguard dignitaries and certain vessels participating in the event. If the Coast Guard deems it necessary to establish such zones at a later date, the details of those zones will be announced separately via the **Federal Register**, Local Notice to Mariners, Safety Voice Broadcasts, and any other means available.

With the arrival of War of 1812 Bicentennial Commemorations participants and spectator vessels in the Port of Baltimore for this event, it will be necessary to curtail normal port operations to some extent. The Coast Guard will attempt to minimize interference while still ensuring the safety of life on the navigable waters immediately before, during, and after the scheduled events.

Discussion of Comments and Changes

The Coast Guard received one comment in response to the NPRM. No public meeting was requested and none was held. What follows is a review of, and the Coast Guard's response to, the issue that was presented by the commenter concerning the proposed regulations.

The commenter stated that while the War of 1812 Bicentennial Celebration will be an important event that normally calls for an increased safety of participating vessels, smaller shipping operations will be unable to afford unforeseen schedule changes, dock workers and their communities will suffer from a lack of labor, and ships unable to access Port of Baltimore terminals may choose to go elsewhere that week and maybe for the foreseeable future; allowing the shipping industry alone to operate as they see fit during the event without the proposed regulations, and providing additional law enforcement patrol resources to monitor the situation, would not cause business losses in the private sector.

We disagree. We feel that as a result of the extensive planning and notice provided to the public, which began in 2009 and will continue through the event, the Port of Baltimore stakeholders and waterway users will not be substantially adversely affected during the event as suggested by the commenter. The highly-publicized, international event is expected to create a large spectator fleet and attract many other waterway users to the area.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. The primary impact of these regulations will be on vessels wishing to transit the affected waterways during the War of 1812 Bicentennial Commemorations vessels arrival beginning on June 12, 2012 and their departure ending on June 20, 2012. Although these regulations prevent traffic from transiting a portion of the Inner Harbor, Northwest Harbor, Patapsco River and the Chesapeake Bay during these events, that restriction is limited in duration, affects only a limited area, and will be well publicized to allow mariners to make alternative plans for transiting the affected area. Moreover, the magnitude of the event itself will severely hamper or prevent transit of the waterway, even absent these regulations designed to ensure it is conducted in a safe and orderly fashion.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate or anchor in portions of the Inner Harbor, the Northwest Harbor and Patapsco River, and the Chesapeake Bay, in Maryland. The regulations would not have a significant impact on a substantial number of small entities for the following reasons: The restrictions are limited in duration, affect only limited areas, and will be well publicized to allow mariners to make alternative plans for transiting the affected areas. Moreover, the magnitude of the event itself will severely hamper or prevent transit of the waterway, even absent these regulations designed to ensure it is conducted in a safe and orderly fashion.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. This rule involves implementation of regulations within 33 CFR Part 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety of waterway users and shore side activities in the event area. The category of water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, canoe and sail board racing. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

Additionally, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule also involves establishing a temporary safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects

33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR parts 100 and 165 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.35T05–0123 to read as follows:

§ 100.35T05–0123 Special Local Regulations for Marine Events; War of 1812 Bicentennial Commemorations, Chesapeake Bay and Port of Baltimore, MD.

(a) *Definitions.* (1) ''Captain of the Port Baltimore'' means the Commander, Coast Guard Sector Baltimore or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Baltimore to act on his behalf.

(2) ''Official Patrol Vessel'' includes all U.S. Coast Guard, public, state, county or local law enforcement vessels assigned and/or approved by Commander, Coast Guard Sector Baltimore.

(3) ''War of 1812 Bicentennial Commemorations Vessel'' includes all vessels participating in War of 1812 Bicentennial Commemorations activities under the auspices of the U.S. Department of Homeland Security Application for Marine Event submitted for the War of 1812 Bicentennial Commemorations activities in Baltimore, Maryland and approved by the Captain of the Port Baltimore.

(4) ''War of 1812 Bicentennial Commemorations arrival'' is the movement of War of 1812 Bicentennial Commemorations vessels in orderly succession as they navigate designated routes in the Chesapeake Bay in Maryland and in the Port of Baltimore while inbound to Baltimore, Maryland on June 13, 2012.

(5) ''War of 1812 Bicentennial Commemorations departure'' is the movement of War of 1812 Bicentennial Commemorations vessels in orderly succession as they navigate designated routes in the Port of Baltimore and in the Chesapeake Bay in Maryland while outbound from Baltimore, Maryland on June 19, 2012.

(b) *Regulated areas.* The following regulated areas are established as special local regulations during the War of 1812 Bicentennial Commemorations in Baltimore, Maryland. All coordinates reference Datum NAD 1983.

(1) ''Arrival Area''. All waters of the Patapsco River, Northwest Harbor and Inner Harbor enclosed by:

Latitude	*Longitude*
39°15′41″ N	076°34′48″ W, to
39°15′05″ N	076°34′44″ W, and
39°14′08″ N	076°33′38″ W, to
39°12′46″ N	076°32′03″ W, to
39°10′25″ N	076°31′01″ W, to
39°12′06″ N	076°29′43″ W, to
39°13′22″ N	076°31′16″ W, to
39°15′40″ N	076°33′34″ W.

(2) ''Departure Area''. All waters of the Patapsco River, Northwest Harbor and Inner Harbor enclosed by:

Latitude	*Longitude*
39°15′41″ N	076°34′48″ W, to
39°15′05″ N	076°34′44″ W, and
39°14′08″ N	076°33′38″ W, to
39°12′46″ N	076°32′03″ W, to
39°10′25″ N	076°31′01″ W, to
39°12′06″ N	076°29′43″ W, to
39°13′22″ N	076°31′16″ W, to
39°15′40″ N	076°33′34″ W.

(c) *Special Local Regulations.* (1) All persons and vessels within the regulated areas must operate in strict conformance with any directions given by the Captain of the Port Baltimore and leave the

regulated areas immediately if the Captain of the Port Baltimore so orders.

(2) Unless otherwise directed by the Captain of the Port Baltimore, all vessels within the regulated areas shall be operated at the minimum speed necessary to maintain safe course.

(3) Persons desiring to transit the regulated area must first obtain authorization from the Captain of the Port Baltimore. To seek permission to transit the regulated areas, the Captain of the Port Baltimore and his designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). All Coast Guard vessels enforcing these regulated areas can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz).

(4) The Captain of the Port Baltimore will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and will notify the public of any changes in the status of the regulated areas by a Marine Safety Radio Broadcast on VHF–FM marine band radio, channel 22A (157.1 MHZ).

(d) *Enforcement periods*—(1) *Arrival Area.* Paragraph (b)(1) of this section will be enforced from 9 a.m. until 9 p.m. on June 13, 2012.

(2) *Departure Area.* Paragraph (b)(2) of this section will be enforced from 6:30 a.m. until 3 p.m. on June 19, 2012.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 3. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 4. Add § 165.T05–0123 to read as follows:

§ 165.T05–0123 Safety Zone; War of 1812 Bicentennial Commemorations, Chesapeake Bay and Port of Baltimore, MD.

(a) *Definitions.* (1) ''Captain of the Port Baltimore'' means the Commander, U.S. Coast Guard Sector Baltimore, Maryland.

(2) ''Designated Representative'' means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Baltimore to assist in enforcing the safety zone described in paragraph (b) of this section.

(3) ''War of 1812 Bicentennial Commemorations Vessels'' includes all vessels participating in War of 1812 Bicentennial Commemorations activities under the auspices of the U.S. Department of Homeland Security Application for Marine Event submitted for the War of 1812 Bicentennial Commemorations activities in Baltimore, Maryland and approved by the Captain of the Port Baltimore.

(b) *Regulated areas.* The following locations are a moving safety zone:

(1) All waters within 500 yards of any War of 1812 Bicentennial Commemorations vessel which is greater than 100 feet in length overall, while operating in the navigable waters of the Chesapeake Bay or its tributaries, north of the Maryland–Virginia border and south of latitude 39°35′00″ N.

(2) All waters within 100 yards of any War of 1812 Bicentennial Commemorations vessel which is greater than 100 feet in length overall, while operating in the navigable waters of the Chesapeake Bay or its tributaries, north of the Maryland–Virginia border and south of latitude 39°35′00″ N.

(c) *Regulations.* The general safety zone regulations found in 33 CFR 165.23 apply to the safety zone created by this temporary section, § 165.T05–0123.

(1) All persons are required to comply with the general regulations governing safety zones found in 33 CFR 165.23.

(2) The Navigation Rules shall apply while within the safety zone described in paragraph (b) of this section.

(3) Persons and vessels intending to transit the area of the safety zone described in paragraph (b)(1) of this section shall operate at the minimum speed necessary to maintain a safe course, unless required to maintain speed by the Navigation Rules, and shall proceed as directed by the Captain of the Port Baltimore or his designated representative.

(4) Entry into or remaining in the area of the safety zone described in paragraph (b)(2) of this section is prohibited unless authorized by the Captain of the Port Baltimore or his designated representative. Persons desiring to transit the area of the safety zone described in paragraph (b)(2) of this section must first request authorization from the Captain of the Port Baltimore or his designated representative. To seek permission to transit the area, the Captain of the Port Baltimore and his designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel, by siren, radio, flashing lights, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore or his designated representative and proceed at the minimum speed necessary to maintain a safe course while within the zone, unless required to maintain speed by the Navigation Rules.

(5) The Captain of the Port Baltimore will notify the public of any changes in the status of this zone by a Marine Safety Radio Broadcast on Marine Band Radio VHF–FM channel 22A (157.1 MHZ).

(6) The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(d) *Effective dates:* This section is effective from June 12, 2012 through June 20, 2012.

(e) *Enforcement periods:* This section will be enforced from 6 p.m. on June 12, 2012 until 9 p.m. on June 13, 2012, and from 6 a.m. on June 19, 2012 until 5 a.m. on June 20, 2012.

Dated: April 24, 2012.

Brian W. Roche,

Commander, U.S. Coast Guard, Acting Captain of the Port Baltimore.

[FR Doc. 2012–11497 Filed 5–10–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0369]

Drawbridge Operation Regulation; Cerritos Channel, Long Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Commodore Schuyler F. Heim Drawbridge across Cerritos Channel, mile 4.9, at Long Beach, CA. The deviation is necessary to allow California Department of Transportation to perform critical repair and replacement of electrical components for drawspan operation. This deviation allows the drawbridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 7 a.m. to 7 p.m. on June 10, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the

docket are part of the docket USCG–2012–0369 and are available online by going to *http://www.regulations.gov*, inserting USCG–2012–0369 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *David.H.Sulouff@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The California Department of Transportation requested a temporary change to the operation of the Commodore Schuyler F. Heim Drawbridge, mile 4.9, over Cerritos Channel, at Long Beach, CA. The drawbridge navigation span provides a vertical clearance of 37 feet above Mean High Water in the closed-to-navigation position and 163 feet in the full open to navigation position. Pursuant to § 117.147, the draw opens on signal; except that, from 6:30 a.m. to 8 a.m. and 3:30 p.m. to 6 p.m., Monday through Friday except Federal holidays, the draw need not be opened for the passage of vessels. Navigation on the waterway is commercial, recreational, search and rescue, and law enforcement.

The drawspan will be secured in the closed-to-navigation position from 7 a.m. through 7 p.m. on June 10, 2012 to perform critical repair and replacement of electrical components for drawspan operation. The alternative path around Terminal Island will be available for routine and emergency navigation. This temporary deviation has been coordinated with commercial and recreational waterway users. No objections to the proposed temporary deviation were raised.

Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 26, 2012.

D.H. Sulouff,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2012–11498 Filed 5–10–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2012–0375]

RIN 1625–AA00

Safety Zone; Milwaukee Harbor, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for annual fireworks events in the Captain of the Port, Sector Lake Michigan zone at various times from 9:15 p.m. on June 9, 2012 through 10:30 p.m. on June 27, 2012. This action is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after fireworks events. During the aforementioned period, the Coast Guard will enforce restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after fireworks events. During the enforcement period, no person or vessel may enter the safety zone without permission of the Captain of the Port, Sector Lake Michigan.

DATES: The regulations in 33 CFR 165.935 will be enforced at various times between 9:15 p.m. on June 9, 2012 through 10:30 p.m. on June 27, 2012.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email CWO Jon Grob, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747–7188, email *Jon.K.Grob@uscg.mil.*

SUPPLEMENTARY INFORMATON: The Coast Guard will enforce the safety zone listed in 33 CFR 165.935, Safety Zone, Milwaukee Harbor, Milwaukee, WI, at the following time for the following events:

(1) *Pridefest fireworks display* on June 9, 2012 from 9:15 p.m. through 10:00 p.m.

(2) *Polish Festival fireworks display* on June 16, 2012 from 10:15 p.m. through 11:00 p.m.;

(3) *Summerfest fireworks display* on June 27, 2012 from 9:15 p.m. through 10:30 p.m.

All vessels must obtain permission from the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative to enter, move within, or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.935 Safety Zone, Milwaukee Harbor, Milwaukee, WI and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port, Sector Lake Michigan, will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port, Sector Lake Michigan, determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

Dated: May 1, 2012.

M.W. Sibley,

Captain, U.S. Coast Guard, Captain of the Port Sector Lake Michigan.

[FR Doc. 2012–11494 Filed 5–10–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2012–0375]

RIN 1625–AA00

Safety Zone; Milwaukee Harbor, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for annual fireworks events in the Captain of the Port Sector Lake Michigan zone at various times from 10:00 p.m. on July 19, 2012 through 11:00 p.m. on July 28, 2012 and then again from 10:15 p.m. through

11:00 p.m. on August 19, 2012. This action is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after fireworks events. During the aforementioned periods, the Coast Guard will enforce restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after fireworks events. During the enforcement period, no person or vessel may enter the safety zone without permission of the Captain of the Port, Sector Lake Michigan.

DATES: The regulations in 33 CFR 165.935 will be enforced at various times between 10:00 p.m. on July 19, 2012 and 11:00 p.m. on July 28, 2012 and then again between 10:15 p.m. and 11:00 p.m. on August 19, 2012.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email CWO Jon Grob, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747–7188, email *Jon.K.Grob@uscg.mil.*

SUPPLEMENTARY INFORMATON: The Coast Guard will enforce the safety zone listed in 33 CFR 165.935, Safety Zone, Milwaukee Harbor, Milwaukee, WI, for the following events:

(1) *Festa Italiana fireworks display* on July 19, 2012 from 10:00 p.m. through 10:45 p.m.; on July 20, 2012 from 10:00 p.m. through 10:45 p.m.; on July 21, 2012 from 10:00 p.m. through 10:45 p.m.; on July 22, 2012 from 10:00 p.m. through 10:45 p.m.

(2) *German Festival fireworks display* on July 27, 2012 from 10:15 p.m. through 11:00 p.m.; on July 28, 2012 from 10:15 p.m. through 11:00 p.m.

(3) *Irish Festival fireworks display* on August 19, 2012 from 10:15 p.m. through 11:00 p.m.

All vessels must obtain permission from the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative to enter, move within, or exit a safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port, Sector Lake Michigan, or a designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.935 Safety Zone, Milwaukee Harbor, Milwaukee, WI and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port, Sector Lake Michigan will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port, Sector Lake Michigan, determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

Dated: May 1, 2012.

M.W. Sibley,

Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.

[FR Doc. 2012–11496 Filed 5–10–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2009–0783); FRL–9669–2]

Approval and Promulgation of Implementation Plans; Commonwealth of Kentucky; Regional Haze State Implementation Plan; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correcting amendment.

SUMMARY: On March 30, 2012, EPA published a rule finalizing a limited approval and a limited disapproval of two revisions to the Kentucky State Implementation Plan (SIP) submitted by the Commonwealth of Kentucky through the Kentucky Energy and Environment Cabinet, Division for Air Quality (DAQ), on June 25, 2008, and May 28, 2010, to address regional haze. In that rulemaking, EPA inadvertently excluded an entry to the table for EPA-approved Kentucky non-regulatory provisions. This action amends the table by adding an entry for Kentucky's regional haze SIP and SIP amendment.

DATES: This action is effective May 11, 2012.

ADDRESSES: Copies of the documentation used in the action being corrected are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Benjamin can be reached at 404–562–9040, or via electronic mail at *benjamin.lynorae@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On March 30, 2012, EPA published a rule finalizing a limited approval and a limited disapproval of two revisions to the Kentucky SIP submitted by DAQ on June 25, 2008, and May 28, 2010, addressing regional haze. *See* 77 FR 19098. In the final action, EPA inadvertently excluded an entry identifying Kentucky's regional haze SIP and SIP amendment in the table of ''EPA-Approved Kentucky Non-Regulatory Provisions'' located at 40 CFR 52.920(e).

II. Action

This action amends the table in 40 CFR 52.920(e) by adding an entry for Kentucky's regional haze SIP and SIP amendment. EPA has determined that today's action falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation where public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. Public notice and comment for this action are unnecessary because today's action, adding an entry in the table located at 40 CFR 52.920(e), has no substantive impact on EPA's March 30, 2012, limited approval and limited disapproval of the regional haze SIP revisions. In addition, EPA can identify no particular reason why the public would be interested in being notified of the correction, or in having the opportunity to comment on the correction prior to this action being finalized, since this correction action does not change the meaning of EPA's analysis or action related to the regional haze SIP revisions.

EPA also finds that there is good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action. Section 553(d)(3) of the APA allows an effective date less than 30 days after publication ''as otherwise provided by the agency for good cause found and published with the rule.'' The purpose

of the 30-day waiting period prescribed in APA section 553(d)(3) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Today's rule, however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, today's action only adds an entry in 40 CFR 52.920(e) identifying EPA's March 30, 2012, limited approval of Kentucky's regional haze SIP. For these reasons, EPA finds good cause under APA section 553(d)(3) for this correction to become effective on the date of publication of this action.

III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action only adds an entry identifying EPA's March 30, 2012, limited approval of Kentucky's regional haze SIP in the table located at 40 CFR 52.920(e), and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Furthermore, this rule does not contain any unfunded mandates or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), given the nature of this action as described above.

This rule does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This rule also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule only adds an entry identifying EPA's limited approval of Kentucky's regional haze SIP in the table located at 40 CFR 52.920(e), and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act (CAA). This rule is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant. In addition, this rule does not involve technical standards, thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule also does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 10, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* CAA section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: April 23, 2012

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart S—Kentucky

■ 2. Section 52.920(e) is amended by adding an entry for ''Regional Haze Plan and Plan Amendment'' to the end of the table to read as follows:

§ 52.920 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED KENTUCKY NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approval date	Explanations
*	*	*	*	*
Regional Haze Plan and Plan Amendment.	Statewide	06/25/08 and 05/28/10.	03/30/12, 77 FR 19098.	Source-specific BART requirements are summarized in Table 7.5.3–2 of the Commonwealth's May 28, 2010 submittal.

[FR Doc. 2012–11183 Filed 5–10–12; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0525; FRL–9340–1]

α-[p-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene); Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) (CAS Reg. Nos. 9036–19–5, 9002–93–1) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. The Joint Inerts Task Force, Cluster Support Team Number 5 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene).

DATES: This regulation is effective May 11, 2012. Objections and requests for hearings must be received on or before July 10, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0525. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; email address: *leifer.kerry@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0525 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 10, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0525, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background

In the **Federal Register** of August 26, 2011 (76 FR 53372) (FRL–8884–9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7858) by Joint Inerts Task Force, Cluster Support Team 5, c/o CropLife America, 1156 15th St. NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) (CAS Reg. Nos. 9036–19–5, 9002–93–1) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations

applied to growing crops and raw agricultural commodities after harvest. That notice referenced a summary of the petition prepared by Joint Inerts Task Force, Cluster Support Team 5, the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Previously, in the **Federal Register** of May 17, 2010 (75 FR 27443) (FRL–8826–3), EPA established a time-limited tolerance exemption for α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) (herein referred to in this document as octylphenol ethoxylate) with an expiration date of May 17, 2012. The 2-year time limitation was established for two purposes:

1. To provide time for the development and submission of confirmatory toxicity data to address equivocal results in the available genotoxicity studies conducted on octylphenol ethoxylate (as described in Unit IV.C., of the May 17, 2010 final rule); and

2. To provide additional time, should the initial testing not confirm EPA's conclusion regarding the lack of a cancer concern, for registrants to attain EPA approval of registration amendments for reformulation of their pesticide products to remove octylphenol ethoxylate and to replace existing products with reformulated products.

In establishing the time-limited tolerance exemption for octylphenol ethoxylate, EPA stated that if the submitted data confirmed its conclusion regarding a lack of cancer concern, the Agency intended to remove the expiration date from the tolerance exemption prior to expiration of the exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for octylphenol ethoxylate including exposure resulting from the exemption established by this action.

In the **Federal Register** of May 17, 2010, EPA issued a final rule establishing an exemption from the requirement of a tolerance for residues of octylphenol ethoxylate when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 with an expiration date of May 17, 2012. EPA has determined that establishing an exemption from the requirement of a tolerance for residues of octylphenol ethoxylate when used as an inert ingredient an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest will not significantly change the risk assessments the Agency relied on to support the May 17, 2010, tolerance action, as explained in this unit.

As part of the Agency's conduct of the risk assessment in support of the May 17, 2010, tolerance action, it was determined that there were no acute, chronic, short- or intermediate term aggregate risks of concern. With regards to aggregate cancer risk, the assessment concluded that based on a weight of the evidence consideration of the available data, the Agency believed that cancer risks would be negligible. However, due to the equivocal findings in the mutagenicity data base, the Agency asked for confirmatory data. Specifically, EPA recommended that supporters of the octylphenol ethoxylate tolerance exemption perform the following studies for confirmatory purposes:

A new Ames assay (OCSPP Harmonized Guideline 870.5100—Bacterial reverse mutation test) and a mouse lymphoma assay (OCSPP Harmonized Guideline 870.5300—*in vitro* Mammalian cell gene mutation test).

A bone marrow assay (OCSPP Harmonized Guideline 870.5395—Mammalian erythrocyte micronucleus test).

Since *in vivo* mutagenicity studies such as the bone marrow assay are generally regarded as more definitive than *in vitro* studies, and a negative result in the bone marrow test may outweigh whatever results are found in the Ames test and mouse lymphoma assay, supporters of the octylphenol ethoxylate tolerance exemption were given the option of conducting the mammalian erythrocyte micronucleus test in lieu of the two *in vitro* mutagenicity studies. If those data did not confirm EPA's cancer conclusion, then EPA would need 2-year cancer bioassays in the mouse and rat (OCSPP

Harmonized Guideline 870.4200—Carcinogenicity (mouse) and OCSPP Harmonized Guideline 870.4300—Combined Chronic Toxicity/Carcinogenicity (rat)) to make a safety finding in support of the tolerance exemption.

In response to the May 17, 2010, final rule, the Joint Inerts Task Force, Cluster Support Team Number 5 conducted an *in vivo* Mouse Bone Marrow Erythrocyte Micronucleus Test Following Oral Administration (OCSPP Harmonized Test Guideline 870.5395) of the representative test compound, poly(oxy-1,2-ethanediyl),α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy- (CAS Reg. No. 9002–93–1). These data were submitted to the Agency on November 12, 2010 (Master Record Identification Number 48293301).

The data were evaluated by EPA and it was determined that the test substance did not induce numerical or structural chromosomal damage, providing further confirmation that octylphenol ethoxylate is not of concern for aggregate cancer risk. Further details of this evaluation can be found at *http://www.regulations.gov* in the document ''Octylphenol Ethoxylates—(JITF CST 5 Inert Ingredients).—Review of Confirmatory Mutagencity Toxicity Data'' in docket ID number EPA–HQ–OPP–2011–0525.

Refer to the May 17, 2010, **Federal Register** document, available at *http://www.regulations.gov,* for a detailed discussion of the aggregate risk assessment and determination of safety.

Therefore, based on this information and the findings in the final rule published in the **Federal Register** of May 17, 2010, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to octylphenol ethoxylate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for octylphenol ethoxylate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 26, 2012.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, the table is amended by revising the entry for the inert ingredient which reads in part ''α-[p-(1,1,3,3-tetramethylbutyl)phenyl]'' to read as follows:

§ 180.910 Inert ingredients used pre and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* * *
α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of p-(1,1,3,3-tetramethylbutyl)phenol with a range of 1–14 or 30–70 moles of ethylene oxide: If a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1–14 or 30–70 (CAS Reg. Nos. 9036–19–5, 9002–93–1).	Not to exceed 7% of pesticide formulation.	Surfactants related adjuvants of surfactants.
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[FR Doc. 2012–11064 Filed 5–10–12; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 00–168, 00–44; FCC 12–44]

Standardized and Enhanced Disclosure Requirements for Television Broadcast Licensee Public Interest Obligations; Extension of the Filing Requirement for Children's Television Programming Report (FCC Form 398)

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission revises its public file regulations to require that television station public inspection files be made available in an online public file to be hosted on the Commission's Web site.

DATES: The rules in this document contain information collection requirements that are not effective until approved by the Office of Management and Budget (OMB). These rules will become effective 30 days after the Commission publishes a document in the **Federal Register** announcing OMB approval of those information collection requirements.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Holly Saurer, *Holly.Saurer@fcc.gov* of the Media Bureau, Policy Division, (202) 418–2120. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, send an email to *PRA@fcc.gov* or contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Report and Order,* FCC 12–44, adopted and released on April 27, 2012. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., CY–A257, Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW., Room CY–B402, Washington, DC 20554. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

The Commission will seek written comments on the Paperwork Reduction Act (PRA) modified information collection requirements in a separate notice that will be published in the **Federal Register**.

Paperwork Reduction Act of 1995 Analysis

This document contains modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, will invite the general public to comment on the information collection requirements contained in this *Second Report and Order* as required by the Paperwork Reduction Act of 1995, Public Law 104–13 in a separate notice to be published in the **Federal Register**. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees. We received one comment specifically addressing this issue. In the present document, we have assessed the effects of the new requirements on small businesses, including those with fewer than 25 employees, in the Final Regulatory Flexibility Analysis (''FRFA'') below.

Summary of the Second Report and Order

I. Introduction

1. In this *Second Report and Order* we modernize the procedures television broadcasters use to inform the public about how they are serving their

communities, by having stations post their public files online in a central, Commission-hosted database, rather than maintaining the files locally at their main studios. This updating of our rules harnesses current technology to make information concerning broadcast service more accessible to the public and, over time, reduce broadcasters' costs of compliance. This Order is another step in our modernization of the Commission's processes to transition from paper filings and recordkeeping to digital technology. Without imposing any new reporting obligation, it will help bring broadcast disclosure into the 21st century.

2. Specifically, we adopt—with significant modifications—the proposal discussed in the *Further Notice of Proposed Rulemaking* (''*FNPRM*'') to replace the decades-old requirement that commercial and noncommercial television stations maintain a public file at their main studios with a requirement to post most of the documents in that file to an online public file to be hosted by the Commission. All permittees and licensees of a TV or Class A TV station in the commercial and noncommercial educational broadcast services must maintain a public inspection file. We have departed from the proposal in a number of respects to maximize public benefits while avoiding compliance costs that the record suggests would not be justified at this time. First, because many stations' existing political files are large, and the retention period for the political file is shorter than for other portions of the public file, we will not require stations to incur the cost of upload their existing political files to the online public file. Rather, stations may upload documents in that portion of the public file only prospectively. Second, broadcasters will be responsible for uploading only those items now required to be in the public file but not otherwise filed with the Commission or available on the Commission's Web site. In particular, the Commission will itself import to the online public file any document or information now required to be kept in the public file and that must already be filed with the Commission electronically in the Consolidated DataBase System (''CDBS''), so that stations do not need to post that information. Third, we do not adopt new disclosure obligations for sponsorship identifications and shared services agreements at this time, as had been proposed in the *FNPRM.* Rather, broadcasters will only be required to place in their online files material that is already required to be placed in their local files. Fourth, we do not impose specific formatting requirements on broadcasters at this time, although stations should upload relevant documents either in their existing electronic format or in a simple, easily created electronic format such as .pdf. Finally, we will provide an organized file system for uploading documents so that the resulting public file for each station is orderly, and organizationally similar for all stations, thus promoting ease of use by stations and the public.

3. To better ensure that the Commission can accommodate television broadcasters' online filings and to limit any unforeseen start-up difficulties to those stations that are best able to address them, we will phase in the new posting requirements. For the next two years we will only require stations that are affiliated with the top four national networks (ABC, NBC, CBS and Fox) and that are licensed to serve communities in the top 50 Designated Market Areas (''DMAs'') to post political file documents online. We exempt all other stations from posting their political file documents to their online public file until July 1, 2014. The Media Bureau will issue a Public Notice no later than July 1, 2013 to seek comment on the impact of this posting requirement, to enable us to consider whether any changes should be made before it takes effect for the other stations. We also defer considering whether to adopt online posting for radio licensees and multichannel video programming distributors until we have gained experience with online posting of public files of television broadcasters.

II. Background

4. One of a television broadcaster's fundamental public interest obligations is to air programming responsive to the needs and interests of its community of license. Rather than dictating how broadcasters must meet that obligation, the Commission affords broadcasters broad latitude, subject to a reporting requirement under which broadcasters must maintain a public inspection file that gives the public access to information about the station's operations.

5. Almost seventy-five years ago—in 1938—the Commission promulgated its first political file rule. That initial rule was essentially identical to our current political file regulation in its requirements that the file be available for ''public inspection'' and include both candidate requests for time and the disposition of those requests, including the ''charges made'' for the broadcast time. More than 45 years ago—in 1965—the Commission additionally adopted a broader public inspection file rule. The public file requirement grew out of Congress' 1960 amendment of Sections 309 and 311 of the Communications Act of 1934 (the ''Act''), which allowed greater public participation in broadcast licensing. Finding that Congress, in enacting these provisions, was guarding ''the right of the general public to be informed, not merely the rights of those who have special interests,'' the Commission adopted the public inspection file requirement to ''make information to which the public already has a right more readily available, so that the public will be encouraged to play a more active part in dialogue with broadcast licensees.''

6. In October 2000, in the first *Notice of Proposed Rulemaking* issued in this proceeding, the Commission concluded that ''making information regarding how a television broadcast station serves the public interest easier to understand and more accessible will not only promote discussion between the licensee and its community, but will lessen the need for government involvement in ensuring that a station is meeting its public interest obligation.'' The Commission tentatively concluded that it should require television licensees to make the contents of their public inspection files, including a standardized form reflecting the stations' public interest programming, available on their stations' Web sites or, alternatively, on the Web site of their state broadcasters association. In 2007, the Commission adopted a *Report and Order* implementing these proposals.

7. Following the release of the *2007 Report and Order,* the Commission received petitions for reconsideration from several industry petitioners and public interest advocates. The industry petitioners raised a number of issues, generally contending that the requirements were overly complex and burdensome. Public interest advocates argued that the political file should be included in the online public file requirement rather than exempted as provided in the *2007 Report and Order.* In addition, five parties appealed the *2007 Report and Order,* and the cases were consolidated in the United States Court of Appeals for the District of Columbia Circuit. The court granted a petition to hold the proceeding in abeyance while the Commission reviewed the petitions for reconsideration. Challenging the rules in a third forum, several parties opposed the *2007 Report and Order's* ''information collection'' under the Paperwork Reduction Act.[1]

[1] The Paperwork Reduction Act of 1995, Pub. L. 104–13, requires that the Office of Management and

8. In June 2011, Commission staff released ''The Information Needs of Communities'' Report (''*INC Report''*), a comprehensive report on the current state of the media landscape created by a working group including Commission staff, scholars, and consultants. The *INC Report* discussed both the need to empower citizens to ensure that broadcasters serve their communities in exchange for the use of public spectrum, and the need to remove unnecessary burdens on broadcasters who aim to serve their communities. The *INC Report* recommended an online system for public inspection files in order to ensure greater public access. It also recommended that stations be required to disclose online shared services agreements and ''pay-for-play'' arrangements. The *INC Report* further suggested that governments at all levels collect and publish data in forms that make it easy for citizens, entrepreneurs, software developers, and reporters to access and analyze information to enable them to present the data in more useful formats, and noted that greater transparency by government and media companies can help reduce the cost of reporting, empower consumers, and foster innovation.

9. In October 2011, the Commission vacated the *2007 Report and Order,* determining that technological and marketplace changes since 2007 may be pertinent to our consideration of television broadcasters' public disclosure obligations, and that the best course of action would be to take a fresh look at the policy issues raised in this proceeding. The Commission also adopted an *FNPRM* to refresh the record in this proceeding. It solicited comment on various proposals, including some of the proposals parties raised on reconsideration, to improve public access to information about how broadcasters are serving their communities while minimizing the burdens placed upon broadcasters.

III. Discussion

10. The updated rules we adopt today modernize disclosure procedures to improve access to station files that, for decades, have been public more in theory than in practice. Today, reviewing a television station's public file typically involves the substantial expense and inconvenience of traveling to the station and paying for paper copies. Under our rules, review will involve a quick and essentially costless Internet search. This modernization is plain common sense. The evolution of the Internet and the spread of broadband Internet access has made it easy for stations to post material online and for many consumers to find information online. The television broadcast industry should not be left out of the online revolution that has improved the delivery of products and services across our economy, as well as the availability of government services and government information to the public.

11. At the same time, we are committed to updating the outdated procedures for public access to television stations' public files in a manner that avoids unnecessary burdens on broadcasters. We have significantly departed from the proposals in the *FNPRM* to achieve this goal. Based on this balance of considerations, the online public file requirements we adopt today will replace the existing in-station retention requirements as follows:

- Each station's entire public file will be hosted online, by the Commission.
- Television broadcasters will be responsible for uploading only those items now required to be in the public file but not otherwise filed with the Commission or available on the Commission's Web site. These items include citizen agreements, certain EEO materials, issues/programs lists, children's television commercial limits records, donor lists for NCEs, local public notice announcements, time brokerage agreements, must-carry or retransmission consent elections, joint sales agreements, Class A continuing eligibility documentation, materials related to FCC investigations (other than investigative information requests from the Commission), and any new political file materials.
- Any document or information now required to be kept in a television station's public file and that must already be filed with the Commission electronically in the Consolidated DataBase System (''CDBS'') will be imported to the online public file and updated by the Commission. This includes authorizations, applications and related materials, contour maps, ownership reports and related materials, EEO materials, The Public and Broadcasting manual, children's television programming reports, and Letters of Inquiry and other investigative information requests from the Commission, unless otherwise directed by the inquiry itself.
- Television stations will not be required to upload their existing political files to the online file; rather, they will be permitted to maintain at the station those documents placed in their political file before the effective date of our rules, and only upload documents to the online political file on a going-forward basis.
- To smooth the transition for both stations and the Commission and to allow smaller broadcasters additional time to begin posting their political files online, we will exempt all stations that are not in the top 50 DMAs and all stations not affiliated with the top four national television broadcast networks, regardless of the size of the market they serve, from having to post new political file materials online until July 1, 2014.
- Stations will not be required to upload letters and emails from the public to their online public file; rather, they will continue to maintain them in a correspondence file at the main studio.
- Stations will not be required to include in their online public file any documents not already required to be included in their local file.

We believe these procedures will substantially advance the original goals of the public file requirements and better enable the public to engage with their local broadcasters. Further, while broadcasters will incur a modest, one-time transitional cost to upload some portions of their existing public file to the Commission's online database, that initial expense will be offset by the public benefits of online disclosure. Over time, moreover, broadcasters will benefit from the lower costs of sending documents electronically to the Commission, as opposed to creating and maintaining a paper file at the station.

A. A Commission-Hosted Online Public File Will Serve the Public Interest

12. We agree with commenters who maintain that placing the public file online will improve the public's access to information and facilitate dialogue between broadcast stations and the communities they serve. As the Commission noted in the *FNPRM,* making public file information available through the Internet should facilitate public access and foster increased public participation in the licensing process. The information provided in the public file is beneficial to persons who wish to participate in a station's license renewal proceeding. For example, as the Public Interest, Public

Budget (''OMB'') approve any information collections. As required, the Commission published a notice in the **Federal Register** seeking comment on the projected burdens of the rules. *See* 73 FR 13462 (Mar. 13, 2008); 73 FR 30316 (May 27, 2008). Because of pending petitions for reconsideration requesting substantial revisions to the *2007 Report and Order* that would affect the projected burdens, the Commission did not formally transmit the information collection to OMB for its approval, choosing instead to address the petitions for reconsideration, and therefore the rules adopted in the *2007 Report and Order* never went into effect.

Airwaves Coalition (''PIPAC'') notes, when broadcasters fall short of their obligations or violate Commission rules, the public's ability to alert the Commission by filing complaints or petitions to deny the renewal of a station's broadcast license is essential, and the public file provides information necessary to file such complaints or petitions.

13. We also agree with commenters that access to the public files has been inconveniently (and unnecessarily) limited by current procedures. Currently, the public can access a station's public files only by visiting the main studio during regular business hours. Several commenters discussed the inconvenience of this limited access and identified problems they experienced in attempting to access stations' public files. Making the information available online will permit 24-hour access from any location, without requiring a visit to the station, thereby greatly increasing public access to information on how a station is meeting its public interest obligations. The Internet is an effective and low-cost method of maintaining contact with, and distributing information to, broadcast viewers. Indeed, given the considerable flexibility that stations have in locating their main studios and the fact that many members of a station's audience may be working during ''normal business hours''—the only time stations are obliged to make the file available—there seems little doubt that 24-hour Internet access would greatly improve the accessibility of these files. The public benefits of posting this information online, while difficult to quantify with exactitude, are unquestionably substantial.

14. We further conclude that it will be efficient for the public and ultimately less burdensome for stations to have their public files available in a centralized location. The Commission will, therefore, host the online public file. A Commission-hosted online public file will allow consumers to easily find the public files of all stations in their viewing area, making the Commission's Web site a one-stop shop for information about all broadcast television stations in a viewer's market and eliminating the need to access multiple stations' Web sites. As we further discuss below, a uniform organizational structure among all files will allow consumers to more easily navigate the public files of all stations of interest. The public will be able to review the online public file of any station, and quickly navigate to where each category of documents is found, because each station's online public file will be organized in the same format.

15. The Commission's hosting of the public file also addresses concerns expressed by many broadcasters about the burden of hosting files online themselves. The rules adopted in 2007 would have required stations to host their public files on their own Web sites. In petitions for reconsideration, two broadcast trade associations proposed that the Commission host the files instead, suggesting that such a solution would be less burdensome to licensees, who would not have to devote resources to creating and maintaining an online public file. They also contended this approach would be more efficient, since many public file items are already filed with the Commission. For instance, the Named State Broadcasters Associations estimated that the Commission's hosting of the files would save broadcasters more than $24 million in first-year costs, and almost $14 million in annual costs thereafter. We agree that having the Commission host stations' public file information will ultimately reduce costs for stations—compared to the existing local file requirements.

16. We agree with commenters who reject the argument that there is no public need that can be met by placing online the political file portion of the station's public inspection file. As noted by commenters, placing the political file online will enable candidates, as well as the public, journalists, educators, and the research community, to identify and investigate those sponsoring political advertisements. Under current rules, the political file must contain, among other things, all specific requests for broadcast time made by or on behalf of a candidate and the disposition of those requests. It must also contain information regarding other appearances by candidates (excluding those in certain news programming exempt from the equal opportunities provision), and information about issue advertising that ''communicates a message relating to any political matter of national importance.'' As noted by some commenters, political ad spending is rapidly increasing, and often the only way to track such expenditures is through stations' political files. We also agree with PIPAC's assertion that the disclosures included in the political file further the First Amendment's goal of an informed electorate that is able to evaluate the validity of messages and hold accountable the interests that disseminate political advocacy. As the Supreme Court stated in *Citizens United* v. *FEC,* ''transparency enables the electorate to make informed decisions and give proper weight to different speakers and messages'' and that, ''[w]ith the advent of the Internet, prompt disclosure of expenditures can provide shareholders and citizens with the information needed to hold corporations and elected officials accountable for their positions and supporters.'' We are also persuaded by commenters claiming that ''the public must have access to information about the messenger as well as the message to fully understand an ad's content.''

17. Campaigns and candidates will be among those who benefit from being able to obtain political file information online. Some industry comments argue that candidates will obtain only limited benefits and possibly experience detrimental effects from moving the political file online. Broadcasters argue that the existing process serves the candidates and the stations well, and there is no reason to believe that changing the process will benefit candidates or campaigns. Other broadcasters argue that it is more meaningful and efficient for a candidate's representatives to speak with a station's sales department on the phone or in person. According to these broadcasters, personal interactions would be lost if the political file were to be placed online, which would be frustrating and create inefficiencies for advertising buyers and station staff. We fail to see how the online availability of past political time purchases will discourage buyers from having contact with the station concerning current and future time buys or how this information's availability will interfere with ongoing relationships between the stations and buyers. The fact that buyers and candidates will have increased ease of access to relevant information should not preclude or hinder candidates or buyers from a continuing dialogue with stations as they purchase time. Although some stations may elect to continue to make information routinely available to candidates through personal interaction at the station during business hours, which we do not intend to discourage, we expect that candidates and their representatives will use the online political file to obtain information from source documents without filtering by station personnel and at any time of day. LUC Media, a candidate media buyer, argues that ''the only way that candidates can make sure that they receive the availabilities and prices that the law requires is to have access to stations' and cable television systems' political files.'' LUC Media claims that the political file is necessary because ''stations and cable television

systems have learned over the years that, if they can limit the information that candidates have about availabilities and rates, they can get candidates to overpay for the airtime that they buy.'' While LUC Media notes that this is not the practice of all stations, LUC Media routinely reviews stations' political files to ensure that they are providing candidates with equal opportunities, which is why ''the Commission requires that this information be available for public inspection.'' LUC argues that ''Internet access to those files will enable more candidates to become better informed about availabilities and pricing and, thus, demand that they receive the lowest unit charge for the time that they buy.'' Internet access will also eliminate the need for such buyers to travel to every station in a market to verify the contents of the public file, and to ask for help from station employees who have to take time away from their normal duties to accommodate such requests. We agree with LUC Media that placing the political file online will enhance the underlying purpose of the political file.

18. Some broadcasters argue that the Commission's focus in this proceeding has inappropriately changed from increasing broadcast dialogue with the public to enabling access to information about the stations for research and public advocacy groups with no ties to the broadcast stations' communities. We do not perceive the dichotomy these broadcasters suggest. While the public file is first and foremost a tool for community members, it is also a tool for the larger media policy community. Public advocacy groups, journalists, and researchers act in part as surrogates for the viewing public in evaluating and reporting on broadcast stations' performance. And as we stated in the *FNPRM,* easy access to public file information will assist the Commission, Congress, and researchers as they fashion public policy and recommendations relating to broadcasting and other media issues. For example, the Commission has said that ''the quarterly issues/programs lists will provide the public and the Commission with the information needed to monitor licensees' performance under this new regulatory scheme and thus permit us to evaluate the impact of our decision. Existing procedures such as citizen complaints and petitions to deny will continue to function as important tools in this regard.'' Academic analysis of such lists help the Commission monitor whether stations are meeting their responsibilities to their local community, and can provide information relevant to citizen complaints and petitions to deny. We recognize the efforts of public interest groups and academics to analyze publicly available information and educate the public about how their local stations are serving their communities, and believe that this work is an important aspect of educating viewers about their local television broadcast stations.

B. Broadcasters' Initial Costs To Comply Will Be Minimized and the Online Public File Will Ultimately Lead to Cost Savings

1. We Are Tailoring the Requirements To Minimize Costs of Moving the Public Files Online

19. We have adopted a variety of measures to minimize the efforts broadcasters must undertake to move their public files online. In addition, we have declined to adopt certain proposals in the *FNPRM* at this time, to further ensure that the costs of compliance with the new posting procedures are outweighed by the benefits of online disclosure.

20. First, we are minimizing burdens on stations by not requiring them to upload documents that are currently part of the public file but which are also filed in the Consolidated DataBase System (''CDBS'') or that the Commission already maintains on its own Web site. The Commission will import these documents into the online public file. Documents that fall in this category include station authorizations, applications and related materials, contour maps, ownership reports and related materials, EEO materials, The Public and Broadcasting manual, children's television programming reports, and Letters of Inquiry and other investigative information requests from the Commission, unless otherwise directed by the inquiry itself. Broadcasters will be responsible for uploading only those items not otherwise filed with the Commission or available on the Commission's Web site.

21. We recognize that stations' need to upload other items in the public file—including citizen agreements, certain EEO materials, issues/programs lists, children's television commercial limits records, donor lists for NCEs, local public notice announcements, time brokerage agreements, must-carry or retransmission consent elections, joint sales agreements, Class A continuing eligibility documentation, materials related to FCC investigations (other than investigative information requests from the Commission), and new political file materials—will entail some burden initially, inasmuch as stations will have to upload electronic versions or scan and upload paper versions of existing public files to the online public file. But not all stations will have all of these documents. For example, a station may not have time brokerage agreements, joint sales agreements, or citizen agreements, and may not be a Class A station. In that situation, there will be nothing in these categories for the station to upload. Moreover, many of the items in the public file will not require frequent updating. An LMA, for example, may have a term of 5 or more years and would not require any further action on the part of the station unless the agreement was amended or replaced. Joint sales agreements, citizen agreements, retransmission and must-carry consent elections similarly involve extended periods of time. In addition, as discussed below, stations will not be required to upload any of their existing political file documents. Rather, stations may upload documents to the political file component of the online public file only prospectively. We conclude that, for those public file items that stations do have to post, the transitional costs would involve only a one-time burden on broadcasters that, as further explained below, we find is outweighed by the significant benefits of transitioning the public file online.

22. Second, we minimize burdens on broadcasters by declining to adopt any new recordkeeping requirements. As discussed below, we are not adopting the proposal in the *FNPRM* to require stations to include sponsorship identification information in the online public files or to include shared services agreements that are not already required to be included in the local file. Instead, only information already required to be included in the local file will need to be posted online.

23. Third, we are not requiring stations to post files online in a particular format at this time. Thus, they will not need to undertake the costs of developing new electronic forms or of conforming their current recordkeeping practices to accommodate a Commission-designed form.

2. Broadcast Commenters Greatly Overstate the Costs Involved

24. Based upon the actions we are taking to minimize burdens, discussed above, and our analysis of some television stations' public files, we conclude that the broadcast commenters vastly overstate the burdens of moving their public files online.

25. The Commission is taking steps to ensure that the process of uploading

files to the online public file—both initially and prospectively—will be simple and efficient. We are developing the online public file system to permit broadcasters simply to drag and drop documents into the relevant folders of their online public file. As a result, although the initial upload of existing documents—that is, those documents maintained in the paper file before the effective date of our new rules—will impose some costs on stations, we do not believe these costs will be unduly burdensome, particularly compared to the resulting benefits.

26. Some broadcasters argue that uploading the existing public file will be unduly burdensome. They argue that we should implement the online public file requirement solely on a forward-looking basis, encompassing either all documents created after a certain date or all documents created after a station's next renewal. Joint TV Broadcasters notes that many materials must be retained until final action is taken on a station's next license renewal application, and a decision requiring all existing local files to be scanned and uploaded would require stations to upload eight years of information that may soon be obsolete. It argues that some of the materials, like the issues/programs lists, commercial limit certifications, and the political file, should be required to be uploaded to the online public file only on a going-forward basis.

27. We find that the one-time electronic upload or scanning and upload of existing documents is not unduly burdensome and that adoption of a grandfathering approach would be confusing to those seeking access to the information. Such an approach would necessitate the continued maintenance of a robust local file, which could diminish the benefits to the public of the online file with respect to improved public access to information, and would diminish the benefits to the stations of moving their files online. We agree with Common Frequency that scanning existing paper documents does not constitute an extraordinary burden, as it is a rote process that can be affordably outsourced if necessary. In addition, if the documents are currently maintained in electronic form, as some are likely to be, the one-time burden will be de minimis.

28. Our determination that the transition process will not be unduly burdensome is based in part on a review, in March 2012, of the public files of stations in the Baltimore DMA. Commenters provided little data based on actual station records. The Commission therefore determined that it was advisable to supplement the record with empirical data from a sample market. Baltimore was selected because its proximity to Commission headquarters in Washington, DC, and the relatively compact size of the Baltimore DMA allowed staff to visit stations there without great difficulty. Our review of the Baltimore DMA public files indicates that most stations will only need to upload a fraction of their existing public file to the online public file—or approximately 250 to 2200 pages, as reflected in the second column of the chart below. Columns three and four reflect what we believe the costs are likely to be for stations to upload this information. We estimate that stations that choose to scan and upload this information in-house can do so for $.10 per page,[2] while stations can outsource such work for approximately $.50 per page. Based on this assumed cost of $.10 to $.50 per page, we calculate a range of the average cost for a station to upload their existing public file in accordance with this Order, with the average cost per station ranging from approximately $80–$400 per station. We believe that this modest one-time expenditure (even if it were not offset by later costs savings as we believe it will be) is worth the benefits of providing the public with access to a station's existing public file.

	Public file pages to upload w/in 6 months [1]	In-house cost per page [1]	Outsourced cost per page	In-house total	Outsourced total
WBAL–TV	998	0.1	0.5	$99.80	$499.00
WMAR–TV	987	0	0	0.00	0.00
WJZ–TV	844	0.1	0.5	84.40	422.00
WNUV	251	0.1	0.5	25.10	125.50
WBFF	2094	0.1	0.5	209.40	1,047
WUTB	2126	0.1	0.5	212.60	1,063.00
WMPT	2180	0	0	0.00	0.00
WMPB	2180	0	0	0.00	0.00
Total	11660			631.30	3,156.50

29. We agree with commenters that, once they incur these modest costs, stations will realize savings by no longer having to keep a local file on a going-forward basis. We recognize that stations will be required to maintain and make publicly available a correspondence file with letters and emails from the public, but we agree with commenters that stations will nonetheless realize significant reductions in burdens by not having to maintain a more robust local file. Placing the information online will minimize disruptions in the daily operation of a station, and reduce the burdens placed on station staff that currently field phone calls and chaperone in-person requests to inspect the files.[3] When Commission staff sought to obtain the public files of the Baltimore stations, as well as those of five other stations around the country, stations dedicated staff resources to

[2] Under the Freedom of Information Act, the Commission is allowed to charge for our research and reproduction services under certain conditions. *See http://www.fcc.gov/guides/how-file-foia-request.* We have determined those costs to be $.10 per page. *See* Modification of the Freedom of Information Act Fee Schedule, D.A. 10–97 (Jan. 19, 2010). We believe this to be an accurate reflection of actual reproduction costs, and we expect that scanning costs would be equal to this or lower, because paper, ink, and fasteners are not required.

[3] Our current rules do not require stations to accommodate political file requests over the phone, because such a requirement could disrupt station operations. We expect that requiring stations to place the public files online will have a similar beneficial effect; reducing rather than expanding, disruptions to operations at the station as station personnel would no longer have to process requests for access to this information in person, as they are currently required to do. Instead of accommodating each candidate or their campaign representatives personally on a frequent basis, an online requirement will allow a station to upload the most up-to-date information periodically for all interested parties. As discussed below, however, we are requiring stations to maintain a back-up of the political file for use in the event the Commission's database becomes unavailable or disabled.

copying the files, and were in no case able to provide the copies on the same day as the request. Further, once broadcasters have completed the initial upload of documents in the existing public files, as specified herein, we do not believe that uploading public file documents on a going-forward basis to an online public file is likely to be any more burdensome than placing such documents into a paper file. Indeed, in many instances, using the online public file will be less burdensome, because uploading (or even scanning, then uploading) a file may be easier and more efficient than photocopying it, walking it to the local paper file, finding the appropriate folder and inserting it in the proper order.

30. The industry's arguments regarding the costs involved with uploading documents to the online public file focus on the political file, which they identify as the most active element of the public file. NAB states that two stations have estimated that the time involved in completing political ad buys will ''essentially double'' in an online environment, at a cost of $80,000 per station. Joint Broadcasters estimates that ''creating electronic versions of all political time requests'' and uploading such documents will take one half hour per record, which would amount to almost 16 hours per week per station during the political season, compared to the 2.5 hours a week that stations spend under the current paper filing system. We find unpersuasive the argument that the time required to assemble the online political file will double or quadruple. Instead of photocopying documents and placing them in a paper public file, stations will upload to the online public file documents already stored in electronic format or scan paper documents (a process akin to photocopying) and upload the electronic versions. One commenter notes that not all stations own a scanner, or a scanner of sufficient quality to make copies of documents adequate for uploading to the Commission's online public file. For stations that do not wish to make this minor investment, other business solutions are available, including creating documents electronically or outsourcing the scanning functions. Scanning costs may be higher on a per-page basis if outsourced, just as it would be more expensive per page to outsource the copying and filing of paper copies. Given that stations will be uploading fewer documents into the online public file than they currently place in their paper files, we expect that station costs going forward will be lower than under the existing requirements. Given that the requirement to drag and drop the files into our online public file will replace the requirement to photocopy and walk the documents to the local file, we expect that fulfilling this requirement will not take substantially more time and may take less time to accomplish. Broadcasters provide no specific support for their facially implausible assertion that creating electronic versions of political file requests and uploading them would take a half hour. Moreover, they fail to acknowledge that the time involved in uploading documents electronically should decrease substantially with time as station personnel become more accustomed to this process.[4]

31. We also disagree with the commenter who projects that the proposed online public file, and specifically the political file and sponsorship identification requirements, will require each station to hire one to three employees at an average cost of $30,000 to $140,000 per station per year. On the contrary, given that the requirement to upload the files will replace rather than add to the existing file requirements, we expect that stations will be able to assign these responsibilities to existing staff, rather than hire additional staff. We fail to see how this requirement could legitimately result in the need to hire three additional staff members, even in the heat of an election. Moreover, the commenters' estimated figures include the costs of complying with the *FNPRM's* proposed new public file requirement for sponsorship identification, which, as we discuss below, we are not adopting. Further, to the extent these figures include costs associated with the initial upload of the existing political file, they overestimate the burden on broadcasters because we do not require the existing political file to be uploaded.

32. We note that because the size of the political file appears to roughly correlate with a station's political advertising revenues, stations with little or no revenue will have little to no obligations under these rules, and stations with larger numbers of pages to upload will tend to have similarly large income associated with those pages. In addition, although candidate advertising must be sold at the lowest unit charge, issue advertisers are not entitled to reduced rates and therefore pay market rates for advertising on broadcast stations. When balanced against the revenues earned from political advertising—which brought broadcasters an estimated $2.29 billion in 2010 and are expected to bring in even more in 2012—the costs of complying with the online posting requirement seem even less significant. Indeed, political files reviewed by Commission staff, from markets across the country, generally reflect that stations receive political advertising revenues of thousands of dollars per page of political file that must be uploaded. We also agree with commenters who note that ad buyers, candidates, and the public must today undertake burdens to obtain information about the political file, including traveling from station to station to obtain political file information. Our collection of the Baltimore DMA public files required, in total, dozens of person-hours, driving back and forth to stations (first to request the copies and then to collect them), and copying costs that were estimated at close to $1,700 by the stations themselves. Our action today will substantially reduce or eliminate each of those burdens.

C. Application of Online Posting Rule to Specific Public File Components

1. Political File

33. We consider public access to stations' political files particularly important. Therefore, we will adopt the proposal in the *FNPRM* that political files be included in the online public file, but will exempt all stations not in the top 50 DMAs, and all stations in the top 50 DMAs that are not affiliated with the top four national television broadcast networks, from posting their political file documents online until July 1, 2014. Prior to this exemption expiring—by July 1, 2013—the Media Bureau will issue a Public Notice seeking comment on the impact of moving online the political files for these 200 stations, to enable us to consider whether any changes should be made before the requirement takes effect for the other stations. In addition, as discussed above, we will not require any stations to upload their existing political file; rather, they will be required to upload new political file content on a going-forward basis.

[4] As discussed further in Section III.C.1 below, stations are required to ''keep and permit public inspection of a complete and orderly record (political file) of all requests for broadcast time made by or on behalf of a candidate for public office, together with an appropriate notation showing the disposition made by the licensee of such requests, and the charges made, if any, if the request is granted.'' 47 CFR 73.1943. We note that political files that Commission staff reviewed frequently contained more information than is required by our rules. Stations that are concerned about the burdensomeness of placing their political file online on a going-forward basis may wish to review their political file retention practices.

34. We believe circumstances have changed to warrant reaching a different conclusion about posting the political file online than we reached in the *2007 Report and Order*. In the *2007 Report and Order,* the Commission excluded the political file from the requirement that stations post their public files on their Web sites. The Commission determined that the frequent requests for access by campaigns and the need for stations to update the file frequently during an election season made an online posting requirement inappropriate. The Commission also reasoned that political campaigns generally have greater resources than individual viewers and, therefore, access to the in-station political file would tend to be less burdensome for campaign organizations. Petitioners for reconsideration argued that such a decision focused exclusively on the interests of the candidates and broadcasters, and not on the public. In addition, as the Commission noted in the *FNPRM,* television stations now handle many political advertising transactions electronically, through emails and a variety of software applications. As a result, requiring stations to make this information publicly available online will impose far less of a burden under current circumstances than under previous conditions. We thus disagree with arguments that the Commission does not have a sufficient basis to reverse the decision of the *2007 Report and Order* to exclude the political file from the online requirement. Our understanding of how stations manage their political transactions and their traffic systems, technological advances that have occurred since the *2007 Report and Order,* and our decision to host and centralize the online public file support our revised approach. Below, moreover, we respond to specific arguments that we should exclude the political file from the online public file.

35. *Electronic Processes.* Some industry commenters argue that our understanding that stations now conduct political advertising transactions electronically is incorrect. They argue that for some candidates the purchasing process is not electronic, but done through a variety of means, including phone, fax, and in person. For political ad buys, the process can be multi-staged. They state that negotiations may result in many entries into the political file before an agreement to provide time is reached. After an agreement is reached, the actual times the advertisement is aired can still change if the spot is purchased on a preemptible basis. Advertising time sold on a preemptible basis means that the advertising spot may be preempted by another advertiser and re-scheduled for another time. In addition, NAB states that national advertising sales representatives communicate with the stations they represent using proprietary software that varies among companies and may not include information about classes of time or rates in the documents they generate, and therefore do not provide sufficient information to fulfill the political file documentation requirements. Thus, these parties argue, stations do not collect information in a uniform manner, and the Commission cannot assume that all of the information that must be in the public file will be included on one form. NAB goes on to explain that billing systems commonly used by stations generate a separate series of reports for each order. During the political season, advertisers generally order time on a weekly basis. A typical billing system will generate three documents for the political file relating to each order—one report showing the original order placed into the station's traffic system, another showing the exact times that spots ran, and a third showing the final charges paid by candidates for those spots. For each order, these reports occupy three to ten printed pages, and for very active advertisers, a weekly report may be much longer. Further, commenters argue that computerized traffic management systems used to sell and schedule television advertising time will not in any way facilitate compliance with an online political file requirement, as there are many different types of automated systems that collect, track, and process information in different ways.

36. Notwithstanding these arguments, broadcasters' record descriptions of how stations actually track advertising purchases and manage the scheduling of such transactions confirms our understanding that stations are capable of, and often do, include electronic processes in their assembly of the political file. While we recognize that there are still some portions of the sales process and political file assembly that are not fully automated, and that some stations use electronic means to a larger extent than others, our review of Baltimore political files confirms that many of the records that would be required to be in the public file originate as or are reduced to electronic files and would thus be relatively easy to upload in a universally readable format, such as .pdf. To the extent that a required document is not automatically converted to electronic form by the sales or invoice and reconciliation process, they can be easily scanned and uploaded instead of photocopied and placed in the paper file, as is the current practice.

37. Furthermore, we reject broadcasters' burden arguments that are based on the fact that existing electronic traffic management systems may not be programmed to allow stations to upload documents directly to a database. According to some broadcasters, each traffic management software system provider would have to program, test, and finalize an export function tailored to the Commission's servers, consuming ''hundreds of thousands of man hours,'' after which broadcasters would have to install this new software on their existing systems, and [t]aken together, these steps would stretch into years, and the costs would be significant.'' Under the rules we are adopting, broadcasters will not need to change the software in their traffic systems to post documents to our online public file, though they are free to do so if that is the approach they wish to take. Rather, stations will either need to save such files to widely available formats such as Microsoft Word (.doc) or rich text format (.rtf), or convert the files to portable document format (.pdf) , and then drag and drop those files to the Commission's online public file. We do not believe that either of these alternatives will impose appreciable increased costs on broadcasters as compared to current requirements.

38. *Increased Access to Lowest Unit Charge Information.* NAB expresses concern about the ''unintended but potentially very real marketplace distortions and consequences that could occur if market sensitive information is readily accessible'' to its competitors. It notes that, in addition to broadcasters, cable operators and DBS providers must also keep a political file, and requiring only broadcasters to place their political file online would ''place broadcasters at a disadvantage vis-à-vis their competitors.'' NAB argues that ''[b]roadcasters could see advertising revenues drop if competitors attempt to use the data in the file to undercut their rates. This disadvantage would directly harm the public,'' NAB continues, ''because, if advertising revenue drops due to disparate regulation, stations would not be able to expand service offerings, and may have to cut back on current offerings.'' Network Station Owners also express concern about making ''[t]his proprietary information * * * available to commercial as well as political advertisers, to other local stations, and to competing advertising

media such as cable operators, newspapers and web sites.'' It argues that because the political file contains ''information on the station's lowest rates on particular programs and rotations,'' placing the political file online will ''afford a significant intelligence advantage to one side in private commercial negotiations. Armed with political file information, the shrewd time buyer's ability to drive the hardest possible bargain would be greatly enhanced by data allowing him to estimate the station's bottom line. One poker player would, in effect, have had at least a partial glance at the other's hand.'' [5]

39. We find that placing this already-public information online will not cause significant market distortions. Furthermore, the benefits of placing the political file online are substantial, and we will not exclude it on the basis of unsubstantiated burden arguments. Broadcasters have failed to provide any evidence to support their claims of commercial harm. We note that several parties raised the claim of ''commercial harm'' in the final weeks prior to adoption of this item, but the filings contain little more than generalized and vague assertions. Most important, we are not requiring broadcasters to make any information publicly available that stations are not already required to make public. Broadcasters have been required to make political file information including rates charged for political advertising, available in some form since 1938, and anyone, including broadcasters' competitors and customers can currently access these data in the paper files. In addition, since 2002, Section 315(e) of the Act has specifically required that the political file include ''the rate charged for the broadcast time.'' Moreover, the public files of broadcasters' competitors have been available in paper form to television broadcasters and the public for years. Given the mutual, long-standing public availability of such documentation and the likely knowledge of this availability among major commercial and political buyers, we do not believe that the increased ease of access to broadcasters' public files will lead to significant distortions in the marketplace. Although we do not know the exact percentage of advertisers and competitors that seek review of information in stations' political files, we are aware they do so on a regular basis, as Commission staff frequently receives calls from stations asking whether or not they must provide such entities access to the political file. As staff has previously instructed in these situations, all members of the public—including advertisers and competitors—are entitled to access a stations' political files. To the extent it is economically beneficial for competitors, potential advertisers, or buyers who seek to represent advertisers, to access this data, they already have the ability to review the material at the stations. Buyers do, in fact, review the political file. We recognize that, because of their economic incentive, competitors and potential advertisers may be more likely to undertake the expense of visiting stations to review the current political files. We expect that having the files accessible online will encourage other members of the public to make use of the political files. Commenters have failed to show that an online posting requirement would alter in any meaningful way the economic incentive of these entities. Moreover, even if it had not been publicly available for decades, online posting of lowest unit charge information would not necessarily lead to marketplace distortions. While the political file lists the lowest unit charge that a candidate receives, it does not reveal significant information about the commercial transaction that established that lowest unit charge. Various factors unknown to another commercial buyer—including that the advertiser establishing the lowest unit charge bought a higher volume of ads, committed to a long-term advertising relationship, or other variables—can justify denying the lowest unit charge rate to a different commercial buyer under different circumstances. In addition, the fact that there are many variables (lengths, classes of time, and time periods) for any given lowest unit charge makes it harder for any potential purchaser to find a lowest unit charge that is comparable to the ad purchase it is seeking to make. These variables also make it difficult to compare the lowest unit charges of competing stations, as the stations may not sell the same classes of time. In the end, stations are in control of setting lowest unit rates, and have final determination of how low they are willing to set their commercial rates. Further, given that the statute expressly requires such information to be placed in the public file, exempting such rate information would be contrary to the statutory directive to make the political file publicly available.

40. *Effect on How Stations Sell Time.* NAB argues that online filing would necessitate changes in how stations sell political advertising time, because ''the variances in the ways in which stations manage political advertising sales and the political file'' would not be compatible with a ''standardization of stations' political file processes.'' These arguments seem to be based on a misunderstanding of our proposal in the *FNPRM.* As the Commission emphasized in the *FNPRM,* the online political file is meant to serve as a source of information to candidates, buyers, viewers, and others, but the actual purchase of advertising time and the receipt of equal time requests will continue to be handled by the station. We reiterate that we are merely

[5] One party also claims that online disclosure of a station's political file will result in an uncompensated government taking in violation of the Fifth Amendment. We disagree. Target Enterprises is a media buyer that claims to have ''buil[t] a proprietary computer statistical model and database'' to enable ''its clients to achieve the most effective media purchases during an election cycle.'' Target claims that an uncompensated taking will result if the details of political ad spending become available online in real-time because Target's ''protected business model and proprietary approach'' will be disclosed to the public and its competitors and thus ''cause the value of the company to be lost.'' We reject Target's takings claim on several grounds. The regulation at issue does not result in a ''physical taking'' because it does not deprive Target of any property right, much less result in a direct appropriation or physical invasion of private property; rather, it requires television broadcast stations to post online information that they already make publicly available at their stations. Indeed, television broadcast stations—not media buyers such as Target—are subject to the online requirement, and thus no direct appropriation or physical taking of Target's property can be shown. *See Loretto* v. *Teleprompter Manhattan CATV Corp.,* 458 U.S. 419 (1982) (to establish a physical taking requiring just compensation, a party must show a direct government appropriation or physical invasion of private property). We note that no broadcast station has raised a takings argument. Similarly, Target has failed to establish the factors required for demonstrating a regulatory taking. *See Penn Central Transportation Co.* v. *City of New York,* 438 U.S. 104 (1978) (identifying several factors for determining what constitutes a ''regulatory taking,'' including the economic impact of the regulation, the extent to which the regulation has interfered with distinct investment-backed expectations, and the character of the government action). Nothing in the Commission's regulations restricts Target's ability to use or keep confidential its computer models, database, or any other alleged ''trade secrets.'' Moreover, Target's claim involves the general health of its business rather than specific property or estimates as to the property's likely diminution of value. As the Supreme Court has explained, unilateral expectations and abstract needs are not sufficient to raise takings concerns. *Ruckelshaus* v. *Monsanto Co.,* 467 U.S. 986, 1005–1006 (1984). Further, the broadcasters subject to the online posting requirement operate in an industry that has long been regulated and thus this regulatory context undercuts the reasonableness of Target's purported expectations. *Concrete Pipe and Products of California, Inc.* v. *Construction Laborers Pension Trust for Southern California,* 508 U.S. 602, 645–646 (1993) (noting, in rejecting the claim of interference with reasonable investment backed expectations, that ''those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end'').

changing the form of disclosure to the public of information already required to be in the public file. We are making no change in the political advertising sales process. Rather, we expect stations to continue handling political ad sales in whatever way is most convenient to them.

41. *Substantive Political File Requirements.* We likewise are not persuaded by arguments that the rules regarding what material must be included in the political file are vague and that, therefore, the Commission should not adopt an online posting requirement. As discussed above, this proceeding simply modernizes the procedures television broadcasters use to inform the public about information they are already required to disclose. If any licensee is unsure about any aspect of our political file requirements, it may request clarification of our existing substantive disclosure rules. To respond to specific questions raised in this record, however, we offer the following guidance. The political file rule requires that licensees ''keep and permit public inspection of a complete and orderly record (political file) of all requests for broadcast time made by or on behalf of a candidate for public office, together with an appropriate notation showing the disposition made by the licensee of such requests, and the charges made, if any, if the request is granted.'' The same information, among other things, must be included with respect to issue advertising containing a message relating to a ''political matter of national importance.'' These issue ads will also need to be included in the online political file, just as they currently need to be included in the local political file. One commenter argues that it is unclear what ''requests'' includes. Although we do not think that term is unclear, we clarify that licensees are required to place in their political files any final orders by candidates for specific schedules of time or availabilities within a specific schedule of time—in other words, orders to buy particular schedules (including programs or dayparts), amounts of time (including spot or program lengths), and classes of time for particular days (such as preemptible spots, Monday-Friday rotations, runs of schedule or specific placements). We note that ''any final orders'' mean orders that station representatives reasonably believe to be a final, agreed-upon order. If the final order is later amended after being included in the on-line political file, a station can replace the previously final order with the amended final order, or may simply upload the amended final order. Licensees are not required to place in their political files general requests by candidates for advertising time stations have available to purchase, or rates for a general array of time.

42. In response to concerns that the term ''disposition'' is unclear, we note our rules define it as ''the schedule of time purchased, when spots actually aired, the rates charged, and the classes of time purchased.'' We clarify that the ''disposition'' of the request does not include a record of the negotiations or back-and-forth discussions between the licensee and the candidate after the request is made. It does include the final, mutually agreed upon order of time, including: classes of time purchased; charges made; as well as any subsequent, relevant reconciliation information about the order, including the times spots actually aired and details such as any ''make goods'' provided for preempted time, and rebates or credits issued.

43. *Existing Political File.* Commenters argue that if we require stations to upload the existing political file, it will be unduly burdensome. Some broadcasters provide projected costs and burdens of placing the political file online. NAB estimates that just uploading the existing political files could take hundreds of hours per station. NAB supported its assertions about the burdens of uploading the existing political file by providing the estimated size of the political file in inches for six stations in six different television markets, ranging in size from 3,150 pages to 8,100 pages. For example, NAB noted that a political file in Burlington, Vermont measured 19.5 inches, which they estimated as equaling 4,388 pages. Free Press argues that such estimates are exaggerated. Free Press states that it visited all of the television stations in Burlington, Vermont, and was unable to find any political file that was as large as the files discussed by NAB. Further, their review found that each political file reviewed contained documents beyond the required two year retention period, illustrating the possibility that ''broadcasters may be mistakenly (and vastly) inflating the size of the political files they actually are required to maintain.'' NAB bases its projections on the largest political file it reported. While we believe that this burden projection is overstated, we recognize that the existing political file may contain the greatest number of pages for broadcasters to upload as they transition to an online public file. Our review of the public files in the Baltimore DMA indicates that the commercial stations' political files were made up, on average, of 1568 pages, and accounted for, on average, 30% of the stations' public files. This excludes letters and emails from the public, which will be retained in the local file. One station's political file was made up of 4079 pages, or almost 70% of its public file.

44. Departing from the proposal in the *FNPRM,* we do not require stations to post the contents of their existing political files to the Commission's online public file. Given the two-year retention period for the political file, broadcasters' investment in uploading existing political files would have a limited return for the public. Likewise, exempting the existing political file will only require broadcasters to continue to maintain a robust local file for a relatively short period. Because of the two-year retention period for the public file and the relatively large size of existing files, we conclude that exempting the existing political file from online posting is a reasonable means of reducing the initial burden of moving public files online.

45. *Small Market and Non-Affiliate Exemption.* Finally, we adopt in part a broadcaster request that we delay online posting of the political file for smaller stations. These commenters argue that we should allow all broadcasters to gain experience working with the online public file system before requiring that they maintain their political file online. As noted above, this proceeding is over a decade old, and we believe it is time to bring the accessibility of the entire public file into the 21st century in as expeditious a manner as is possible.

46. We are persuaded, however, that it is appropriate to allow certain stations additional time to begin uploading the political file. As discussed further below, because the contents of the political file are time-sensitive, stations must place records in the political file ''immediately absent unusual circumstances.'' We believe it is appropriate to require stations with a greater market reach to undertake this time-sensitive transition first, as they will be more likely to have dedicated resources to address any implementation issues that arise, if necessary. Therefore, we will temporarily exempt stations that are not affiliated with the top four national television broadcast networks (ABC, CBS, NBC and Fox) in the top 50 DMAs and all stations that serve markets below the top 50 DMAs, regardless of affiliation, from including their political file in their online public file for two years. We note that this exemption is permissive, not mandatory. If any station that falls within this exemption prefers instead to immediately

transition to the online political file, it is permitted to do so. This exemption will ease implementation for broadcasters during the initial transition to the online public file, while also giving the Commission time to ensure that the online public file system is implemented effectively.

47. We believe that exempting stations that are not affiliated with the top four networks (ABC, CBS, NBC and Fox) in the top 50 DMAs, and those stations in markets below the top 50 DMAs, creates an exemption threshold that is clear, easy to establish and implement, and not often subject to significant change. Other options for identifying the class of stations to exempt do not provide the certainty that this clear definition provides. For example, an exemption for the top four ranked stations in each market would create a threshold that is often subject to change, would be difficult to measure and administer, and would provide uncertainty to broadcasters, as they are not as able to predict or control ratings. The Commission has used a DMA and affiliation-based standard in other contexts, and we believe it is appropriate to use in this instance.

48. Moreover, while this exemption will ease the initial implementation for broadcasters, it will nonetheless provide the public with online access to the political files of stations garnering the vast majority of political advertising time and money. Stations affiliated with the top four broadcast networks often provide the highest-rated programming, and therefore the most-watched advertising, including a large proportion of political advertising. Based on numbers provided by Kantar Media, we find that these 11 percent of stations, which reach 65 percent of Americans, account for roughly 60 percent of the total television political advertising dollars spent in each major election cycle. Affiliated stations are also more likely to have dedicated IT resources to resolve issues that may arise with implementation of the online political file in the expeditious manner that will be necessary for the political file. Stations that will be exempt initially from the rule generally have smaller political files than the affiliates in the top 50 DMAs, and therefore the public will not be deprived of online access to substantial amounts of political file information during the limited exemption period. In our review of the political files of the Baltimore DMA, the political files of the stations that will be exempt averaged 247 pages, which is substantially smaller than the political files for the stations affiliated with the top four networks, which averaged 2104 pages. In addition, we believe that the approximately two years of experience that stations will gain by transitioning the rest of the online public file will help to ensure that they are prepared to upload the political file. We also believe that delayed implementation for stations with a smaller market reach will ensure that the Commission is able to target assistance to these stations, if necessary. Commission staff will gain experience with the process of assisting the smaller first wave of broadcasters transitioning to the online political file. This will enable staff to more efficiently assist the larger number of stations that will transition later, who may need enhanced support because of their more limited IT resources.

49. As part of our efforts to evaluate the effect of this transition, the Media Bureau will issue a Public Notice by July 1, 2013 seeking comment on the impact of these rules. This Public Notice will give commenters—including the initial group of stations to use the online political file, stations that have yet to transition, and members of the public that review the online political file—an opportunity to provide the Commission with information regarding the impact and utility of the online political file. The Public Notice will enable the Commission to consider whether any changes should be made before the requirement takes effect for the other stations.

50. As discussed above, we do not believe online posting of the public file, including prospective posting of the political file, will impose an unreasonable burden on any television broadcaster. Nevertheless, if licensees not covered by the two-year exemption believe filing new political file materials online will impose an undue hardship, they may seek a waiver of this requirement. Stations seeking waivers should provide the Commission with information documenting the economic hardship the station would incur in complying with this requirement, its technical inability to do so or such other reasons as would warrant waiver under our general waiver standards.

51. *Authority.* No commenter challenged the Commission's authority to require online posting of the public file generally, but NAB suggests that the Commission lacks authority to require the placement of station political files online, and that we therefore must carve out the political file from the rest of the public file. In supplemental comments, NAB argues that in the Bipartisan Campaign Reform Act of 2002 (''BCRA''), Congress expressly required that the IRS and FEC make certain election-related records available online, but did not do so for the items required to be placed in broadcasters' political files. They assert that ''the clear implication is that Congress did not intend for broadcasters to be subject to an obligation to place their political files online and thus, the FCC lacks authority to impose such a requirement absent further legislative action.'' NAB further argues that ''[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.''

52. We find NAB's argument unpersuasive. NAB overlooks relevant facts relating to the adoption of BCRA. First, in adopting the political file retention requirements of Section 315(e) of the Communications Act as part of BCRA, Congress explicitly required that ''a licensee shall maintain, and make available for public inspection, a complete record of a request to purchase broadcast time'' and that ''[t]he information required under this subsection shall be placed in a political file as soon as possible and shall be retained by the licensee for a period of not less than 2 years.'' In doing this, Congress essentially codified the existing political file regulations as reflected in Section 73.1943 of our rules at the time, and placed no new restriction on the Commission's discretion to implement the public-access policy. That is particularly significant because, at the time of BCRA's passage, the Commission had tentatively concluded in this very proceeding that stations should place their public inspection files—including their political files—online. Congress was presumably aware that moving the political file online was actively being considered by the Commission, and expressed no intent to prevent such updating of the rules. Congress instead placed no restriction in BCRA on how the Commission may direct stations to make the political file ''available for public inspection.'' Because the statute is silent on the question of how stations should make the political file ''available for public inspection,'' the Commission, as the expert agency required to implement the Communications Act's provisions, has discretion in determining how to do so, provided that the Commission's decision ''is based on a permissible construction of the statute.'' Given this context, we do not believe that ''available for public inspection'' equates to ''available only in paper format and not online,'' as NAB asserts. We instead believe that this

requirement of availability for public inspection allows us to require that such records be made available for public inspection online, particularly given the ubiquity and general expectation of electronic access to records today.

53. NAB also argues that ''[i]t is apparent that Congress intended the FEC to be the central repository of campaign information.'' From this, they argue that requiring the political file to be placed online would constitute ''duplicative disclosure.'' This argument overlooks the explicit requirement in Section 315(e) that stations ''maintain, and make available for public inspection, a complete record of a request to purchase broadcast time.'' NAB seems to be arguing that the statute, rather than our proposed regulation, is unnecessary and duplicative. The Commission ''must give effect to the unambiguously expressed intent of Congress.'' Here, that unambiguous intent is that the Commission require stations to make the contents of the political file, as outlined in the statute, ''available for public inspection.'' Both the existing requirement, and the proposed online update, give effect to the expressed Congressional intent. We note as well that NAB's arguments regarding the Commission's authority are contradictory—in the first argument, NAB wants to read BCRA's lack of language concerning an online file strictly, and in the second, it wants to ignore the political file statutory provision entirely. We conclude that neither reading is correct. NAB also quotes the FCC's comments in an FEC proceeding in 2002, which stated that the FCC's creation of an online database to comply with BCRA ''could be extraordinarily complex and will require the expenditure of substantial resources in terms of time, money and personnel.'' NAB goes on to say that ''[t]he online posting burdens that the FEC proposed to impose on the FCC ten years ago and that caused the FCC to express concern are different from those the agency proposes to impose on television stations today. But the issues here about the burdens that would be imposed on stations by the FCC's online file proposals ''in terms of time, money and personnel'' are similarly entitled to respect and weight.'' As discussed in detail in the text, we have afforded considerable respect and weight to broadcasters' assertions about the burdens involved with posting their public files online, and have adopted a number of measures intended to reduce those burdens without sacrificing the goals of this proceeding.

54. Furthermore, the information filed with the FCC and the FEC is substantially distinct and intended for different purposes. The FEC was established by Congress to regulate federal elections, and FEC reporting requirements are limited to federal elections. The FCC's political file, by comparison, requires disclosure of information regarding all elective offices, including federal, state and local. The FCC's broadcast political file must be made ''available for public inspection'' in part to notify candidates of information pertaining to transactions by an opponent. This notification is necessary in order to assess candidates' equal opportunities rights under Section 315 corresponding to an opponent's purchases of ad time. The FEC does not collect any of the specific data that would be useful to candidates in connection with their equal opportunities rights, all of which appear in the political file, including: ''(A) Whether the request to purchase broadcast time is accepted or rejected by the licensee; (B) the rate charged for the broadcast time; (C) the date and time on which the communication is aired; (D) the class of time that is purchased.'' Instead, the spending data collected by the FEC requires candidates to disclose the aggregate amount expended during the period of time covered by the disclosure to a particular payee, the mailing address of the payee, the purpose of the transaction(s), the candidate's name and federal office sought, and the date of disbursement. Typically, candidates make their television advertising purchases through media buyers. Thus, under the FEC's aggregate disclosure requirements, a candidate would only need to disclose the funds provided to a media buyer without disclosing how the media buyer allocated such funding—whether it goes to television, radio or print media, let alone how much was paid to each television station. There is no requirement to identify the specific components of the ad-sales transactions that broadcasters include in their political files, making the FEC disclosures nearly useless for a candidate seeking equal opportunities or learning what rates their opponents paid or the schedule of time purchased, and useless to members of the public who are seeking information about the purchasers of specific advertisements being carried on their local television station.

55. *Immediacy.* Consistent with our current political file rules, we adopt the *FNPRM's* tentative conclusion that stations must upload records to their online political file ''immediately absent unusual circumstances.'' Whether maintained at the station or online, the contents of the political file are time-sensitive. For example, a candidate has only seven days from the date of his or her opponent's appearance to request equal opportunities for an appearance.

56. We do not believe that complying with the longstanding immediacy requirement will be any more difficult when uploading to an online public file than when placing paper in a local file; in fact, using the online public file should often be quicker and more efficient. Some commenters claim that uploading the political file to the online public file immediately absent unusual circumstances is either extremely burdensome or technically impossible, with no public benefit. These commenters state that political advertising buys are fluid and often made at the last minute. They also point out that the final documentation indicating when spots are aired and how much is charged for them is typically generated only on a monthly basis. They note that for this reason, the Commission has advised that rather than having to generate special documents, stations should provide the name of a contact person who can provide parties reviewing the political file with the times specific spots aired. NAB argues that if stations were required to update the online political file to reflect the times that spots aired on a daily basis, that could entail filing more than 100 pages per day of traffic reports in addition to the materials already required to be in the political file. Other commenters argue that moving the political file online will not lessen disruptions to station operations, because the delayed final disposition information about when a spot was aired is information that candidates are interested in obtaining from the station, and stations will still need to field daily in-person inquiries from buyers seeking this information.

57. These arguments generally suggest that online filing would involve a change to existing substantive requirements for assembling the public file. Under our existing rules, however, the political file must include all requests for broadcast time made by candidates, the final disposition of that request, and the charges made. The *FNPRM* did not propose to change these record-keeping requirements, and we do not do so.[6] We understand that stations

[6] We are not persuaded by alternative proposals, one by News Corporation and another by a coalition of broadcast station groups, to adopt additional record-keeping requirements for stations with

generally place initial requests and the final order agreed to between the candidate and the station into the political file immediately, consistent with our rules. We also understand that stations do not routinely place documentation relating to reconciliation information—including the times spots actually aired and details such as any make goods for preempted time, rebates, or credits issued—in the political file on a daily basis. Stations instead make station personnel available to answer questions about final reconciliation in person, by email, or over the phone, and place written documentation about the final disposition in the file at a later date consistent with business practices—usually when final billing is compiled for the purchaser on a monthly basis. This practice is permitted. As the Commission stated in the *Political Rules Reconsideration* decision, ''stations need not be required to employ extraordinary efforts to place immediately in the political file the exact time that candidate spots aired * * *. [I]t will be sufficient to provide information concerning the spots and program times that were ordered by the candidate, with a notation that the station will, upon request, provide immediate assistance and access to the station logs or other definitive information concerning actual air time.'' We are not changing this precedent or practice. We are merely requiring that the materials that stations currently copy and place in their local files on a daily basis now be uploaded to the online public file on a daily basis, and that other information be uploaded consistent with existing business practices as previously approved under Commission precedent. In addition to making this information available online, stations are free to continue making this information available over the phone to candidates and their representatives, if that is their preferred business practice, and as long as that courtesy is extended to all candidates and their representatives. Modernizing public inspection procedures for material in the public file will not increase stations' costs of communicating information that is not yet in the public file.

58. Finally, some commenters argue that the existing political file system works adequately for stations and candidates, and that it is unreasonable to make the political file available immediately online for the benefit of researchers and other members of the public.[7] Network Station Owners assert that the interests of researchers, scholars and citizens in having access to information about political spending ''is not immediate and can be satisfied by visiting the station either during or after the election campaign.'' These commenters seem to be arguing that the needs of stations and candidates are singularly important, and that if these constituencies are not seeking changes to how the political file is maintained, then no changes are warranted. We disagree. First, as LUC Media points out, candidates will benefit from real-time posting of the political file. Supporting that view, the record indicates that the online political file will be used by candidates, their representatives, and the general public. Second, as discussed above, the statute does not prioritize any potential users of the political file; it broadly mandates that the materials be made ''available for public inspection * * * as soon as possible,'' which the Commission has long interpreted to mean available to all members of the public ''immediately absent unusual circumstances.'' The Named State Broadcasters Association expresses concern that ''public advocacy groups and the Commission will play 'stop watch' roulette if the political files were to go online.'' They state that the base fine for political file rule violations is $9,000 and that ''the FCC will have a strong incentive to find at least technical shortcomings in every television station's efforts to comply with the mechanics of a new online political file requirement,'' potentially exposing them to large fines ''notwithstanding the good faith efforts of staff-constrained broadcasters.'' We reject this reasoning. First, if such an enforcement incentive exists, it would exist now with the existing public file rule. Second, as discussed throughout this proceeding, our aim in making the public file available online is to make it more accessible to the public. Commenters' unsupported speculation about possible arbitrary enforcement provides no basis for maintaining the obsolete paper filing system. Moreover, we reject the Named State Broadcasters Association's argument that the base fine for public and political file violations'' should be lowered, an issue that is beyond the scope of this proceeding.

59. *Orderliness.* The Commission will design the online public file with an organizational structure that will ensure that the contents of the file, including the political file components, are orderly and easily uploaded and downloaded. The Commission's rules require licensees to keep ''a complete and orderly'' political file. The Commission stated in the *FNPRM* that it expected licensees to upload any political file information to the online file in an organized manner so that the political file does not become difficult to navigate due to the sheer number of filings. For an online political file to be useful, the Commission acknowledged, candidates and members of the public must be able easily to find information that they seek. The Commission asked whether it should create federal, state, and local subfolders for each station's political file, and whether it should allow stations to create additional subfolders within the political file.

60. NAB recognizes that there are efficiencies in the Commission creating some organizational categories for stations to use, and argues that ''to the extent that the Commission can do this in a timely and accurate manner, for both the general and primary elections for every race in the country where

respect to the political file. The proposal initially advanced by the coalition of broadcast station groups was that we not require stations to make their entire political files available online, but rather require online posting—on either the Commission's or the station's Web site, at the station's election—certain aggregate data concerning candidate purchases of advertising time, with weekly or monthly updates. An expanded coalition later advanced a revised proposal that would require stations to upload certain aggregate data concerning candidate purchases of advertising time, with updates daily, every second day, or weekly. News Corporation, on the other hand, submitted a proposal that would provide stations with the option of either placing their political files online or putting summary information (but not individual rates) in the online public file, while requiring stations to continue to maintain a paper file at the station that includes the rate information. While we appreciate the efforts of these parties to develop alternatives, we believe that these options will deprive the public of the benefits of immediate online access to all the information in the political file. These suggested approaches would impose a new substantive public file reporting obligation on stations, which would be contrary to our goal of limiting the burdens on broadcasters. Furthermore, our political file disclosure requirements take into account a candidate's equal access opportunities afforded under the statute. Under our rules, these rights exist for only 7 days; therefore, to be of value in this regard stations must post political file information immediately. The proposals requiring stations to post information every other day during the equal opportunity period (or even every day in the week before an election), would have limited value to candidates seeking to exercise their equal opportunities rights.

[7] Joint TV Broadcasters argued that ''even PIPAC, the entity urging the FCC to require stations to post their political files online has recognized that the political file can change daily during the election season and has suggested that the online posting requirement 'could include provisions for a reasonable delay in posting updated information.' '' They contend this supports their conclusion that it would be difficult for stations to upload this information ''in real time.'' The commenter fails to note that with respect to burdens, PIPAC actually stated its belief that ''placing this information online will reduce the burden on broadcasters that often receive multiple daily in-person requests to access this information during an election season.'' In their comments, PIPAC ''strongly supports'' the public file proposal discussed in the *FNPRM.*

candidates and issue advertisers may purchase advertising on a local TV station, NAB agrees that it would be desirable.'' We agree with NAB that it would be desirable and less burdensome on broadcasters for the Commission to create specific organizational subfolders, not only for candidate ad buys, but also for issue ads that relate to a political matter of national importance.

61. NAB also argues that the Commission should continue its policy of allowing broadcasters to manage their political file in a manner consistent with their particular operational and sales procedures. It expressed concern that if the Commission creates a rigid standardized organizational structure, they will have to redesign their traffic management systems, which would expand the burdens on broadcasters by interfering with systems that stations use and that are tailored to their own circumstances. NAB argues that the Commission should provide broadcasters with the flexibility to create their own subfolders and ''subcategories'' in order to further organize the data, and recommends that the Commission consider employing the services of a third-party Web-based file hosting service such as Dropbox. To facilitate broadcasters' use of the online file, we will create and propagate subfolders for candidates and will provide stations with the ability to create additional subfolders and subcategories in compliance with their own practices. We also agree with NAB that the use of hosting services providing a mechanism to allow stations to drag and drop files and folders to the online public file will allow for greater efficiencies. We delegate to staff the authority to incorporate such efficiencies, and to cooperate with industry as it develops specifications to enable such efficiencies and to incorporate them in the online system, to the extent the staff concludes that such approaches are workable and effective. We also delegate to staff the authority to design, add to, or adjust the features of the online public file, as needed, to increase its ease of use.

2. Letters From the Public

62. Responding to commenters, we exempt letters and emails from the public from the online public file, instead requiring that such material be maintained at the station in a correspondence file. In the *FNPRM,* the Commission proposed that letters and emails from the public, which now are required to be included in the local file, should not be incorporated in the online public file, but instead continue to be retained at the station for public viewing in a paper file or an electronic database at the station's main studio. The Commission tentatively agreed with reconsideration petitioners that privacy and burden concerns were significant enough to merit excluding these documents from the online public file, and sought comment on its findings.[8] Alternatively, the Commission asked whether it should allow or require stations to redact personally identifiable information before posting letters and emails online. Some commenters, broadcasters and public interest advocates agree that letters and emails from the public should not be placed online due to privacy concerns and the burdens of review and redaction that such concerns would necessitate. Some broadcasters believe that stations should maintain a correspondence file available locally at the station, while others think we should eliminate the requirement entirely. Common Frequency argues that privacy concerns are exaggerated, since it is common for members of the public to comment on publicly available Web sites.

63. We are concerned that requiring correspondence to be placed in the online public file may result in violations of the Children's Online Privacy Protection Act (COPPA), which prohibits posting children's personally identifiable information online. Commenters agree with our privacy concerns. Our review of the public files in the Baltimore DMA indicates that letters and emails from the public can account for up to one third of a station's public file. Thus, requiring stations to review these documents for compliance with COPPA before uploading them to the online public file could pose a burden, which our decision avoids. Therefore, we will not require stations to post this information in the online public file.

64. At the same time, we do not believe that the requirement to retain correspondence from the public should be eliminated entirely. Letters and emails are required to be made available to the public under our rules, and this proceeding is about updating the accessibility of the public file, not about changing its underlying requirements. We will require stations to maintain in a paper file, or electronically on a computer located at the main studio, a publicly available correspondence file at the station. As currently required, this file will include all letters and emails from the public regarding operation of the station unless the letter writer has requested that the letter not be made public or the licensee feels that it should be excluded due to the nature of its content, such as a defamatory or obscene letter. We also note that NCE commenters have requested that we clarify that noncommercial educational stations are not required to retain letters and emails in their public inspection files. This request for clarification stems from an inadvertent error in the draft rules published in the *FNPRM.* We confirm that NCE stations are not required to retain letters and emails from the public, and note that the rule changes reflect this. We emphasize that we are not imposing a new requirement here, but merely retaining the existing requirement for retaining correspondence consistent with our rules.

65. The *FNPRM* also sought comment on a proposal by PIPAC to require stations to report quarterly on how many letters they have received from the public. PIPAC was the only supporter of this proposal. Another commenter noted that such reporting would be burdensome for broadcasters, some of whom receive thousands of pieces of viewer correspondence in a year. We are not persuaded that a mere count of letters received would be of substantial value to the public or the Commission. We thus conclude based on the current record that the burdens of tabulating and reporting on such correspondence cannot be justified, and we do not require it.

66. The Commission also sought comment on whether stations should have to retain comments left by the public on social media Web sites, like Facebook, and tentatively concluded that such information should not be required to be maintained in the correspondence file. Those who addressed this issue agree with our tentative conclusion that, because social media posts are already accessible to the public, the burden of requiring stations to place such material in a correspondence file would outweigh any benefit. We adopt this assessment, and will not require stations to retain social media messages in their correspondence file.

67. Common Frequency suggests that email comments to the station can be standardized for all stations through a comment form on the Commission-

[8] The Commission also sought comment about whether other public file information raises similar privacy concerns. We received very little input on this issue, and will not make any other privacy-based exemptions to the online public file. Our Privacy Threshold Analysis (''PTA'') of the online files indicates that the files to be posted may contain personally identifiable information (''PII''). Consequently, the Commission will be preparing a Privacy Impact Analysis (''PIA'') and a Privacy Act system of records notice (''SORN'') to govern the handling of PII in the station files.

hosted public file Web site, and all commenters could be directed to this form. We decline to adopt this requirement. We do not believe that the Commission is the proper forum to shape the dialogue between a local station and its viewers. Rather, we seek to encourage direct communication between the station and its viewers. As discussed below, the online public file will contain contact information for each station. We encourage members of the public to relay their concerns directly to the station.

3. Other Components of the Online Public File

68. *Contour maps.* We adopt the tentative conclusion that the contour maps available on the Commission's Web site are sufficient for the online public file. Our rules require that the public file contain ''[a] copy of any service contour maps submitted with any application tendered for filing with the FCC, together with any other information in the application showing service contours and/or main studio and transmitter location.'' In the *FNPRM,* the Commission noted that maps showing stations' service contours are available on the Commission's Web site, and are derived from information provided by stations in CDBS. The Commission tentatively concluded that these contour maps available on the Commission's Web site are sufficient for the online public file as they provide the necessary information regarding a station's service contours. Only one commenter discussed this issue, agreeing with the Commission that these contour maps are sufficient. We ask that stations review these maps and contact the Media Bureau if they believe they contain any inaccuracies.

69. *Main Studio Information.* We will adopt the proposal in the *FNPRM* that we require stations to include in the online public file the station's main studio address and telephone number, and the email address of the station's designated contact for questions about the public file. Given that the correspondence file will still be publicly available at the station, along with the existing political file (until its retention period expires in two years), and because we seek to encourage an open dialogue between broadcasters and the viewing public, we believe this information is necessary to assist the public. Stations with a main studio located outside of their community of license should list the location of the correspondence file and existing political file, and the required local or toll free number. Joint TV Broadcasters argues that if access to the public file is to be facilitated by means of online posting, the justification for government regulation of a station's main studio location, at a minimum, erodes substantially. We disagree with this assertion, which is in any event beyond the scope of this proceeding. The Commission has previously stated that a main studio is necessary to maintain reasonable accessibility of station facilities, personnel, and information to members of the station's community of license, which enables the residents of the community to monitor a station's performance, encourages a continuing dialogue between the station and its community, and integrates a station into the activities of the community in order to be more responsive to local community needs in its programming. Although as a result of our action today most required information about the station will be available online, the other benefits cited here, as well as access to the elements of the public file that will not be posted online, continue to support maintenance of a local main studio.

70. *The Public and Broadcasting manual.* We adopt the tentative conclusion that television stations will no longer be responsible for making available ''The Public and Broadcasting'' manual in their public files. We received no comment on this issue. As discussed in the *FNPRM,* the Commission will make this manual prominently available on the Commission-hosted online public file Web site once it is created. The staff is directed to ensure that this manual is updated to reflect the online public file requirements we adopt here.

71. *Issues/programs lists.* We adopt the proposal requiring stations to post their issues/programs lists to the online public file until the Commission adopts changes to this requirement. Broadcasters' public files currently must include issues/programs lists, which are lists of programs that have provided the stations' most significant treatment of community issues during the preceding quarter. The Commission stated in the *FNPRM* that it planned to expeditiously seek comment in a new proceeding to investigate replacing the issues/programs list with a standardized disclosure form, which it did last November in a *Notice of Inquiry.*

72. In that *Notice of Inquiry,* the Commission noted that it remains dedicated to addressing the problem of the lack of access to consistent and uniform information about television broadcasters' programming. Despite the shortcomings of the current state of the issues/programs lists, however, for now this is the best source of information the public has when investigating how a broadcaster's programming is meeting the community's needs and interests. A group of stations commenting as Four Commercial and NCE Licensees argues that the public has minimal interest in viewing this information, and until there is a standardized reporting form, issues/programs lists should not be placed online because they are voluminous and might include program guides that may not be easily uploaded. We disagree that the public has minimal interest in viewing this information. Public advocacy commenters PIPAC and Common Frequency point out that issues/programs lists are the only requirement that broadcasters have to disclose how they are providing community-responsive programming, and agree with the Commission that these lists should be posted to the online public file on a quarterly basis until the Commission implements a new standardized form. When creating the issues/programs list requirement, the Commission declared that one of a broadcaster's fundamental public interest obligations is to air programming responsive to the needs and interests of its community of license, and described the issues/programs list as ''[t]he most significant source of issue-responsive information under the new regulatory scheme.'' Moreover, the list is a significant source of information for any initial investigation by the public or the Commission when renewal of the station's license is at issue. Because of the importance of the issues/programs lists, we conclude that any burden imposed upon broadcasters to upload such information is justified, and find that the lists must be available to the public in the online public file.

73. *FCC investigations and complaints.* Our rules currently require that stations retain in the public file ''material having a substantial bearing on a matter which is the subject of an FCC investigation or complaint to the FCC'' of which the station is aware. The Commission sought comment in the *FNPRM* on whether the Commission should post published sanctions, including forfeiture orders, notices of violation, notices of apparent liability, and citations, in a station's online public file. The Commission also asked whether licensees should be required to upload their responses, if any, to such Commission actions. The Commission noted that this is the sort of information that the public would want to find in reviewing a licensee's public file, that this is a natural extension of the requirement to retain Commission

correspondence, and that parties could seek confidential treatment of particular information in the filings, if necessary. Common Frequency argues that the Commission should require broadcasters to post all materials relating to complaints, petitions, and Commission orders, because the public has a right to know how a broadcaster is conducting its business.

74. The public is entitled to review information regarding Commission investigations and complaints and we consider the scope of the disclosure rule for this material to be quite broad, although we also recognize that premature publication can hamper an investigation and that privacy concerns counsel some limitations on the online posting of some of this information. We conclude that, subject to any disclosure limitation included in a Commission inquiry itself or directed by the staff, the online public file must include Letters of Inquiry (''LOI''), any supplements thereto, and any other correspondence from the Commission commencing an investigation, materials related to such inquiries, licensee responses to these Commission inquiries, and any documents—including Commission orders—terminating or concluding the investigation or imposing penalties as a result of the investigation. We agree that public access to this type of information concerning a station—information that could be key to a full understanding of a station's performance of its duties as a licensee—is important and conclude that it must be placed in a station's online public file. This material is relevant to any member of the public that wishes to participate in a station's license renewal process or to otherwise review and evaluate the service a station is providing to its community of license. We will therefore adopt the tentative conclusion in the *FNPRM* that stations' online public files should contain all material relating to a Commission investigation. Unless directed to the contrary by the Commission (in an LOI or otherwise), stations will be responsible for uploading any materials related to a Commission investigation or inquiry that they generate or possess (such as responses to LOIs and relevant documents related to an investigation). To reduce burdens on stations, the Commission, as it deems appropriate, will post to the online public file any material that it originates relating to an investigation, such as LOIs and other investigative requests. The Commission will also post to the online public file any complaint or complaints that it possesses and that underlie an investigation, if doing so is feasible, will not interfere with or obstruct an investigation and disclosure is consistent with any privacy concerns that publication might raise. When there are circumstances in investigatory and enforcement contexts that would weigh against the disclosure of Commission investigations and related materials, the Commission or the staff may inform a licensee that a Letter of Inquiry or request for information or other material related to a particular investigation need not be placed in the public file or uploaded to the online public file. In the *FNPRM,* the Commission acknowledged concerns expressed in reconsideration petitions about posting to the online public file any material that is the subject of an indecency investigation or complaint, and tentatively concluded that such concerns were unfounded because such material is relevant to the renewal process and the Commission already posts information relating to indecency investigations, such as Notices of Apparent Liability and Forfeiture Orders, on its Web site. As is the case today, stations filing responsive materials subject to a confidentiality request may place copies of their filings into the online database with the confidential material redacted.

75. With respect to complaints that have not prompted an LOI or other investigative request, whether filed with the Commission or submitted only to the station, we believe local retention in the station's correspondence file is appropriate. We conclude, as a general matter, that privacy concerns weigh against routine online posting of these complaints. The Commission or relevant Bureaus on delegated authority, however, may expressly direct a licensee to post such complaints—ones not related to any Commission investigation or inquiry—to the online public file, or it may do so itself, if circumstances warrant.

76. A few commenters argued that the Commission should not require broadcasters to include information about erroneous or meritless allegations in the online public file. They argue that these claims may be unsubstantiated, and that persons with interests adverse to a broadcaster would have an incentive to file false or irrelevant complaints to establish a record tarnishing the broadcaster's character that could be used against it in the license renewal process, and that the increased accessibility to such false claims will increase such incentives. As discussed above, we are not requiring stations to include complaints that are not the subject of a Commission investigation in their online public files, though they are required to include them in their local correspondence files unless the Commission specifies otherwise. We believe that commenters' concern about erroneous or meritless allegations is adequately addressed by allowing stations to include their responses to such complaints in their correspondence files. As discussed above, stations are required to include in their public files responses to Commission investigations, unless directed otherwise in the LOI. As the Commission and the courts are the final arbiters of whether allegations are meritorious, we will not allow individual stations to decide whether particular investigations and complaints against them should be kept out of the public file.

77. *EEO and Children's Requirements.* Under the Commission's equal employment opportunity (''EEO'') rules, all broadcast stations that are required to create an EEO public file report are also required to place their most recent annual report in their public file and post a link to the report on their Web site, if they have a Web site. This requirement was established in order to facilitate meaningful public input, as the public has a ''right to participate in the process of monitoring and enforcing our EEO Rule, which directly impacts them.'' We will continue to require that stations make their EEO materials available on their Web sites, if they have one. In an effort to reduce burdens on broadcasters, however, we will permit stations to fulfill this Web site posting requirement by providing on their own Web site a link to the EEO materials on their online public file page on the Commission's Web site.

78. Similarly, in light of our decision in this Order to require stations with Web sites to provide a link to the online public file on their homepage, we will not require that stations with Web sites also post copies of their Children's Television Programming Reports (FCC Form 398) on their Web sites. In the *Further Notice of Proposed Rulemaking* in MM Docket No. 00–44, the FCC sought comment on whether broadcasters should be required to provide their completed Form 398s on their own Web sites. Members of the public interested in viewing a station's Form 398 will be able to locate that filing from the online public file and, therefore, we do not believe it is necessary to require stations to post the forms on their own Web sites.

79. *Existing Public File Sponsorship Identification Requirements.* Although, as discussed below, we do not impose new sponsorship identification reporting requirements, we also do not exempt existing public file requirements

regarding sponsorship identification from the online posting requirement. Specifically, we decline the request by the National Religious Broadcasters (''NRB'') to exempt from the online public file the disclosure of material required in Section 73.1212(e) of our rules—namely, where ''material broadcast is political matter or matter involving the discussion of a controversial issue of public importance and a corporation, committee, association or other unincorporated group, or other entity is paying for or furnishing the broadcast matter,'' stations must disclose ''a list of the chief executive officers or members of the executive committee or of the board of directors of the corporation, committee, association or other unincorporated group, or other entity.'' We note that the rule also states that ''[i]f the broadcast is originated by a network, the list may, instead, be retained at the headquarters office of the network or at the location where the originating station maintains its public inspection file.'' In addition, Section 315(e) of the Act, added by BCRA, requires that with respect to messages relating to any ''political matter of national importance,'' the political file must contain ''the name of the person purchasing the time, the name, address, and phone number of a contact person for such person, and a list of the chief executive officers or members of the executive committee or of the board of directors of such person.'' This information must be included in the political file, and therefore must be posted to the online file along with other political file information Requiring that this information be included in the online public file should impose little burden on broadcasters, as this information is already being maintained in the local file.

80. In addition, we reject NRB's argument that making such lists available via the Internet will violate citizens' First Amendment rights to enjoy a level of privacy and anonymity regarding their political, social, moral, and religious values and beliefs, and associations. NRB argues that this will have a chilling effect on citizens' willingness to participate in political campaigns. PIPAC responds that making such already-public records available via the Internet does not change the substance of the existing retention requirement. We agree. In addition, we find NRB's argument that this disclosure will chill citizens' speech overstated, as the disclosure requirement in Section 73.1212(e) of our rules applies to executives and board members of sponsoring organizations; it does not relate to individuals' campaign contributions or other political activities. We note also that the FEC requires candidates committees to report to the FEC the identity of individuals who contribute more than $200 to a candidate's campaign. The identity includes the individual's name, mailing address and occupation, as well as the name of his or her employer. We also agree with PIPAC that courts, in evaluating First Amendment challenges, have embraced disclosure of sponsors of political advertisements as promoting speech and discussion, not chilling it. As the Supreme Court stated in *Citizens United* v. *FEC,* ''transparency enables the electorate to make informed decisions and give proper weight to different speakers and messages'' and that ''[w]ith the advent of the Internet, prompt disclosure of expenditures can provide shareholders and citizens with the information needed to hold corporations and elected officials accountable for their positions and supporters.'' Similarly, the First Circuit determined that state laws requiring disclosure of the names of board members on political action committees ''neither erect a barrier to political speech nor limit its quantity. Rather, they promote the dissemination of information about those who deliver and finance political speech, thereby encouraging efficient operation of the marketplace of ideas.''

4. Proposals To Increase the Public File Requirement Rejected

81. We decline to adopt any new disclosure obligations with respect to sponsorship identifications and shared services agreements at this time. While we continue to believe that the public would likely benefit from further information regarding sponsorship identifications and shared services agreements as discussed in the *FNPRM,* we believe it inadvisable to impose new reporting requirements at the same time stations are transitioning to the online public file. We wish to ensure that this *Second Report and Order,* in all major respects, involves changing only the form of disclosure and location of material already required to be included in the public file. We discuss both of these categories below.

82. *Sponsorship Identifications.* We will not at this time require new written disclosure of sponsorship identifications in the online public file, as proposed in the *FNPRM.* Section 317 of the Communications Act requires that broadcasters disclose to their listeners or viewers at the time of broadcast whether material was aired in exchange for money, services, or other valuable consideration. The Commission's sponsorship identification rules implement these provisions and require that stations provide an on-air disclosure when content is paid for, furnished, or sponsored by an outside party. With the exception of sponsored political advertising, and certain issue advertising that must be disclosed in writing, these rules require that stations make an on-air disclosure only once during the programming and that the disclosure remain on the screen long enough to be read or heard by an average viewer. The implementing rule has long had an additional public file recordkeeping component for political and controversial issue announcements, as discussed further below. The *FNPRM* noted that the *INC Report* discussed examples of ''pay-for-play'' arrangements at local TV stations, where ''advertisers have been allowed to dictate, shape or sculpt news or editorial content.'' Despite our decision not to add new reporting requirements, we continue to believe that issues pertaining to sponsorship identification and ''pay-for-play'' are important. We will continue to monitor the use of these practices, and enforce the statute as appropriate.

83. While we agree with commenters that additional written sponsorship disclosures—posted to a station's public file—would benefit the public by addressing the shortcomings of sometimes fleeting on-air disclosures and would provide valuable information that is otherwise difficult to collect, we are also persuaded that we lack sufficient information at this time to properly evaluate the burden that complying with this requirement would impose.

84. *Sharing Agreements.* We also decline to adopt the tentative conclusion that stations include sharing agreements in the online public file. In the *FNPRM,* the Commission asked whether sharing agreements among licensees, such as local news sharing and shared services agreements, should be available in the online public file.

Some broadcasters argue that the disclosure of sharing agreements is beyond the scope of this proceeding, and should be considered in a separate proceeding. They argue that the Commission must first solicit comment and determine the legal status of such agreements. They argue that there has been no determination that shared services agreements are relevant to compliance with any Commission rules or standards, unlike time brokerage agreements and joint sales agreements, which the Commission has deemed to

have attribution implications, and which are required to be placed in the public file. Some note that the recent 2010 Quadrennial Review seeks comment on sharing agreements, and argue that it would be premature to require disclosure of sharing agreements prior to the conclusion of that review. We disagree that the Commission must first address the appropriate regulatory status of such agreements prior to requiring their disclosure, as disclosure itself could inform those decisions and the Commission has wide latitude to impose such a requirement. Nonetheless, we decline to impose this new requirement on broadcasters as they transition to the online public file. We will continue to monitor this issue, and revisit a disclosure requirement either in this proceeding, or in the ownership proceeding, as suggested by broadcasters. Because we decline to adopt this requirement, we will not address comments pertaining to the scope of shared services agreements covered by this proposal.

D. Format of the Online Public File

85. We will not establish specific formatting requirements for documents posted to the online public file at this time. Some commenters promoted making the data well-structured, as searchable as possible, and downloadable. PIPAC argues that the online public file should be searchable by text within the documents, and also by station, state, date, element of the public file and any other metadata contained in the file. They further argue that the file should provide an easy-to-use graphic interface in addition to an API, as these both provide searching and downloading of documents and metadata en mass. We agree that certain information in the public file would be of much greater benefit to the public if made available in a structured or database-friendly format that can be aggregated, manipulated, and more easily analyzed; this continues to be our ultimate goal. We agree with PIPAC, however, that converting the files to this format would take time and money, and the online public file should not be delayed in order to make all of the material in it available in such a manner. PIPAC argues that this will likely result in the submission of documents in non-searchable, non-machine readable format, but it believes this proposal represents a reasonable trade-off between maximizing searchability and the need to expedite access to broadcasters' online public files. We agree that this trade-off is reasonable, and adopt the Commission's tentative conclusion that the benefits of an online public file should not be delayed. At this time we therefore will not require broadcasters to undertake the burdens of altering the form of documents already in existence prior to posting them to the online public file. We observe, though, that even without mandating that documents be filed in a particular format, our creation of a centralized, orderly public file will facilitate search and analysis across all elements of stations' public files.

86. We adopt the *FNPRM*'s proposal to require stations to upload any electronic documents in their existing format to the extent feasible. For example, to the extent that a required document already exists in a searchable format—such as the Microsoft Word .doc format or non-copy protected text-searchable .pdf format for text filings, or native formats such as spreadsheets in Microsoft .xml format for non-text filings—broadcasters are expected to upload the filing in that format to the extent technically feasible. PIPAC agreed with our proposal to require stations to file documents in their native electronic format. We understand that it may be difficult for stations to provide older material that has been in the public file for some time in its native format. In those instances, we understand that stations may need to scan these materials for electronic upload into the online public file. We expect that the need to do this will diminish over time.

87. Also consistent with the *FNPRM,* the Commission will use optical character recognition on public file materials that are scanned, and by default are non-searchable. The Commission asked in the *FNPRM* whether, to the extent documents are posted in a non-searchable format, the Commission should digitize the documents and perform optical character recognition (''OCR'') on them. PIPAC agrees with the Commission's suggestion that if a broadcaster posts a record in only a non-searchable format, the Commission should use an OCR tool to permit maximum searchability. PIPAC notes that commonly available document formats—including Microsoft Word .doc, .txt, .pdf or .odf—can be searched, and can easily be converted into a .pdf file that can be processed by an OCR tool so the contents can be loaded into a searchable database. But commenter Ryan Thornburg notes that OCR software is expensive and faulty, and prefers that the Commission require well-structured formats. For the reasons discussed above, we decline to do so at this time. We determine that, when appropriate, the Commission will use OCR. OCR will be used when text cannot be extracted from the uploaded document format. When documents are uploaded to the online public file, documents that are not in recognized formats will be automatically pushed into OCR, which will scan the document to extract as much text as possible.

88. *Metadata.* We will not require stations to create or preserve metadata in the online public file. In the *FNPRM,* the Commission asked whether users should be able to determine when each item was uploaded to the file, whether the Commission should make available metadata about who uploaded the item, and if there were any concerns about metadata disclosures for confidential or privileged information. NAB anticipates that many stations may use software that removes metadata from its documents for reasons of confidentiality, privilege, or privacy, and does not see value in disclosing who uploaded a document, other than differentiating between documents uploaded by the Commission versus a station. The Sunlight Foundation noted that as long as each station provides contact information, there is no need for the metadata to identify the individual who uploads a filing. We agree, and determine that stations using software that removes metadata will not be required to make any modifications. Given that we will be requiring station contact information, as discussed above, we do not believe that it is necessary to make metadata information available as part of the online public file. However, the Sunlight Foundation also argues that being able to identify the time and date of a filing is important, as it helps to track the most recent version of a particular filing, and allows the user to create a timeline of submitted files. This information, which is captured by the system as files are uploaded, does not generate similar privacy concerns as the metadata contained within the documents uploaded by stations. Our system may present information on the date and time of a filing to users.

E. Implementation

89. Having concluded that broadcast television stations must upload the contents of their public file, other than the political file and letters from the public, to a Commission-hosted online public file, we next discuss issues relating to implementation of the new posting procedure. As with our consideration of all the issues covered by this Order, our resolution of implementation issues is guided by a commitment to creating an online public file experience that is not

burdensome for broadcasters, and is as useful as possible for the public.

90. *Cloud-Based Solution.* We plan to develop the online public file in accordance with the Federal Government's ''Cloud First Policy'' which directs agencies to default to scalable and elastic, cloud-based solutions for increased reliability at lower cost. The public file, consisting entirely of publicly disclosed material, is ideal for leveraging the cloud-based hosting solutions. We anticipate being able to design an online public file that is highly available, scalable, cloud-based, and eliminates any user wait times associated with processing documents after upload. We expect that this will enable stations to upload public file material in a timely fashion, including uploading political file material promptly even during times of increased traffic prior to elections.

91. We disagree with broadcasters who argue that their experiences trying to file the revised Form 323 ownership reports suggest a Commission-created database would suffer from implementation problems. These commenters represent that it can take hours to upload just one attachment to the revised Form 323, and that the political file contains similarly large documents. They argue that such delays would be unacceptable with respect to the political file, where timely access is so important. We agree that it is essential that stations are able to upload public file documents, and particularly political files, efficiently, and that the online public file should be able to handle many stations uploading documents at the same time even during an election season. We recognize problems stations have experienced uploading the revised Form 323 and are working to fix those problems. But we do not anticipate similar problems with respect to uploading the public file. The delays in the Form 323 uploading process stem from the time required in the current Form 323 filing application to validate the large spreadsheets that must be filed with Form 323, and the validation queuing process. Public file documentation will not be subject to the validation process that is required for the Form 323 spreadsheets, nor will we need to impose a similar queuing system necessitated by the validation process. Furthermore, Form 323 was launched and run on existing FCC infrastructure. Since then, the Commission has begun utilizing scalable cloud-based IT architecture solutions to enhance the agency's capabilities. In particular, the Commission anticipates using for online public files the same scalable architecture that currently is being used successfully for the Customer Proprietary Network Information certification document filing system and the National Broadband Map.

92. *Back-up Files.* In lieu of requiring stations to maintain back-up copies of all public file materials, as proposed in the *FNPRM,* the Commission will generate copies of their online files. With respect to the political file, however, we will require stations to maintain local electronic back-up files to ensure that, in the event our online public file were to become temporarily unavailable, they can comply with their statutory obligation to make that information available to candidates, their representatives, non-candidate political time buyers and the public generally as soon as possible. To minimize any burden imposed by this requirement, we have developed tools to allow stations to easily copy mirrors of their online public files, which contain the political files.

93. In the *FNPRM,* the Commission proposed that stations retain electronic copies for back-up purposes of all public file items in the event the Commission's online public file were to become unavailable or disabled. The Commission also proposed that in such circumstances, stations would have to make these back-up files available to the public. We are persuaded by commenters, however, that requiring stations to maintain back-up copies of all public file materials and to make them routinely available directly to the public would reduce the efficiencies of placing the public file online. These commenters explain that such an approach would force stations to continue maintaining a separate complete public file on site so as to comply with the Commission's rules at a moment's notice.

94. To ensure that stations' public files are available even if the Commission's online public file were to become temporarily unavailable or in the event technical problems prevented broadcasters from accessing the Commission's online file, we will create ''failover'' backups of the online public file, including mirroring daily snapshots of the public file. That is, the Commission will make a mirror copy of each station's public file records daily to ensure that if the data in the online public file is compromised, the public files can be reconstituted using the back-up copy. Thus, the Commission will relieve stations of the burden of maintaining a back-up of the entire public file locally. In addition, with the exception of the political file, discussed below, will not make stations responsible for making available to the public information from the public file in the event the Commission's online files become temporarily inaccessible; the mirroring approach will enable us to perform the back-up function ourselves. Although we will not require stations to maintain back-up copies of the public file, stations are free to maintain back-up materials and to continue to make the public file available locally or on their own Web site, in addition to on our Web site, if they choose to do so. To the extent the public may experience a delay in accessing the information due to the brief unavailability of the online file, we consider that delay (with the exception of the political file), on balance, to be acceptable in order not to burden broadcasters with the necessity of making public file materials available to the public at the station. If the Commission's online file becomes temporarily inaccessible to stations for the uploading of new documents, however, stations must maintain those documents and upload them to the online file once it becomes available again for upload. The Commission will also daily make the mirror copy of every station's public file available for the station or other interested parties to download so that, if they wish, they can periodically download a complete mirror of their public file or automate a periodic synchronization.

95. As suggested in the *FNPRM,* we conclude that additional steps should be taken to ensure that access to the political file is not compromised. Accordingly, if the Commission's online public file were to become temporarily unavailable, stations will be required to provide any information pertaining to the political file not just to candidates, their representatives and other political time buyers, but directly to any member of the public as well. The benefits of making such information available immediately outweigh the burdens of maintaining this limited back-up requirement. Given the short seven-day deadline for candidates to request equal opportunity appearances, it is essential to candidates' exercise of their rights under the Act that they have prompt access to political file information. Moreover, limiting that access to candidates and their representatives would be inconsistent with the Communications Act, which requires that political file information shall be ''available for public inspection'' and ''placed in a political file as soon as possible.'' These requirements do not distinguish between candidates and their representatives and other members of the public. In addition, although only

candidates have rights to equal opportunities and lowest unit charge under Section 315, other members of the public may also have time-sensitive needs to access a station's political files. For example, a sponsor of a political issue advertisement may have a significant interest in ascertaining which candidates or other issue advertisement sponsors have bought time at a station.

96. The Commission is taking all steps necessary to ensure that the Commission-hosted online public file will not become unavailable, and we expect instances of unavailability to be both rare and of short duration. As a result, we do not expect the requirement to provide back-up access to the political file during any times of outages to be overly burdensome. In addition, we will allow stations to retain such information in whatever form is most convenient for them. Our making mirror copies of stations' public files available to stations, as described above, will enable stations to comply with the political file back-up requirement with little burden. That is, while not required, stations may choose to meet the political file back-up requirement by periodically downloading a mirror copy of the public file. When choosing this option, stations will need to ensure that they retain any political file records that have not been uploaded or were uploaded after their last download of a mirror copy of their online public file. This means that if a station decides to download a mirror copy of their online public file on a weekly basis, it will need to maintain at the station, in paper or electronic form, any documents that have not been uploaded or that it uploaded to the online political file after its last weekly download. If a station chooses to download a mirror copy of their online public file on a monthly basis, it will need to maintain at the station any documents that have not been uploaded or that it uploaded to the online political file after its last monthly download. If a station chooses not to download a mirror copy of their online public file, and does not otherwise satisfy the back-up requirement, it will need to maintain at the station all documents required to be in its online political file. We stress that stations will only be required to make these backups available if and during such time as the Commission's online public file is unavailable, which we believe will only happen in rare instances, such as national or localized emergencies, because the Commission will follow necessary protocols for creating failover backups of the online public file.

97. *Compliance Dates.* In order to facilitate a smooth transition to the online public file, we will provide a phase-in period for stations to begin uploading files. Stations will be required to begin using the online public file after the effective date of this Order, which is 30 days after the Commission announces in the **Federal Register** that OMB has completed its review under the Paperwork Reduction Act and approved the collection.[9] After the effective date, if a station determines that any document must be placed in the public file, that document must be posted to the online public file. We refer to this as the requirement to post documents online ''on a going-forward basis.'' In order to ensure that broadcasters have time to familiarize themselves with the online public file, the Commission will make a version available to the public soon after adoption of this item. We also instruct the staff to help educate broadcasters about the online public file and how it functions.

98. To ensure that existing public file materials—that is, the public file as it exists prior to the effective date—are uploaded to the online public file in an orderly manner, we will give broadcasters sufficient time to do so. Stations will be permitted to begin uploading existing public file materials immediately after the effective date, at the same time stations must also begin posting online documents on a going-forward basis. Stations must complete the process of uploading the existing public file within six months after the effective date, *i.e.,* six months after the Commission publishes a notice in the **Federal Register** announcing OMB approval under the Paperwork Reduction Act. We believe that giving stations six months to complete the upload of existing files will provide broadcasters adequate time and flexibility to undertake this process.

99. *Accessibility for People with Disabilities.* In the *FNPRM,* the Commission stated that it intended to ensure that the online public files, like the rest of the Commission's Web site, is accessible to people with disabilities. Under Section 508 of the Rehabilitation Act, federal agencies must ensure that members of the public who have disabilities and who are seeking information or services from a federal agency ''have access to and use of information and data that is comparable to the access to and use of the information and data by such members of the public who are not individuals with disabilities.'' For federal agencies, including the Commission, this requires access by people with disabilities to the agencies' Web sites, including electronic filing systems, such as the Commission's ECFS. In the *FNPRM,* we sought comment on whether further actions were necessary to ensure compliance with respect to the online public file. No commenters raised concern about this issue. To assure compliance, the Commission will perform accessibility tests and address any known issues once the online public file has been created. We believe that Commission compliance with the requirements imposed by Section 508 of the Rehabilitation Act will be sufficient to ensure that the online public file is accessible to individuals with disabilities. If we learn of any problems with accessibility of the online public file, we will revisit this issue.

100. *Geographic Coverage Area.* The Commission's online public file will be available to anyone who has Internet access, regardless of their location. Two petitioners on reconsideration of the *2007 Report and Order* suggested that broadcasters should be permitted to limit online public file access to viewers within a station's geographic coverage area. The Commission concluded in the *FNPRM* that it saw no reason to limit online access to the public file, nor did it know of a workable mechanism for implementing and enforcing such a proposal. No commenter opposed this tentative conclusion, and commenters in support agreed that limiting access to a station's public file to viewers within a station's viewing area would be misguided. We believe it entirely consistent with Congressional intent in adopting Section 309 of the Act to enhance the ability of both those within and those beyond a station's service area to participate in the licensing process. We see no additional burdens, and several benefits, in providing full access to the public file of each station. We note, moreover, that such a restriction would reduce the scope of public access now provided by our rules—a result clearly at odds with our objective of increasing the transparency and availability of public records. We conclude that each station's online public file will not be limited to viewers within its geographic coverage area.

[9] Public Law 104–13. The Commission previously sought comment on the paperwork burden associated with these proposals. See 76 FR 72144 (Nov. 22, 2011). Because the Order today substantially adopts the item as proposed in the *FNPRM,* with the exception of a few proposed collections that we are declining to impose, a 30 day public comment cycle will be appropriate. 5 CFR 1320.11(h). The Commission will publish a notice in the **Federal Register** regarding the reduced paperwork burdens adopted in this Order. The OMB review process will then commence.

101. *Maintenance.* In order to keep each public file orderly, we conclude that stations must actively maintain their online public file, although the Commission will ensure that items filed in CDBS are updated in the public file as they are updated on CDBS. In the *FNPRM,* the Commission proposed that stations would be expected to maintain their online public files, ensuring that the files contain the information required by the public file rules and that items be removed once they no longer must be retained under our rules.[10] In response, APTS and PBS argue that it would be more efficient for the Commission automatically to replace old materials when new materials are imported into the public file. They argue that it is inefficient and burdensome for stations to be required to monitor the addition and deletion of materials. They also argue that the Commission should avoid introducing contradictory objectives by punishing stations for sharing information above and beyond what is required while still expecting the stations to increase disclosure so the public is informed of the station's broadcast services.

102. We believe it is important that stations maintain orderly public files. While one of our goals is increased disclosure, another is to be able to provide the public with relevant information in an efficient manner. We are concerned that if material is never removed from the online public file, it will be difficult for the public to find information that is relevant. We note that public file items have different document retention periods, and recommend that stations remove such items in a timely fashion. We do not require stations to remove each item at the end of its retention period, but note that stations are still required to maintain an orderly file. Each station's online public file should not become so overgrown with out-of-date documents that it is difficult to access relevant materials. To assist with this process, the Commission will strive to facilitate the identification and management of aging materials. The Commission will explore creating a mechanism to automatically identify documents that may be beyond their retention period, and flag such documents for station review. Some categories of documents, such as time brokerage agreements and joint sales agreements that need to be retained for as long as the items are effective, will need active management on the part of the station. At a minimum, we will require stations to remove expired contracts when and if replacement agreements are uploaded. Materials in the online file will be disposed of consistent with the records schedule we will develop under the Federal Records Act.

103. *Certification.* We decline the request of two parties that the Commission remove a question on renewal Form 303–S that asks whether local public file documents have ''been placed in the station's public inspection file at the appropriate times.'' The two parties argue that this certification will be unnecessary, since the online public file will be available for anyone to evaluate for completeness. We disagree. Although the Commission will be importing into the online public file all items that are filed with the Commission in CDBS, stations will still be responsible for uploading to the online public file all other items required under our rules. In order to upload information into its online public file, a station will need to log in with the same credentials used to file station applications and materials in CDBS. This will ensure that only station licensees will be able to post information to their files. As there will still be a requirement that stations maintain their public files, it is necessary that stations certify to their compliance with this requirement at the time of license renewal. This certification requirement is designed to promote voluntary rule compliance. In addition, as noted in the *FNPRM,* a successful upload of a station's public file on the Commission's Web site will not be considered agency approval of the material contained in the filing. The purpose of online hosting is to provide the public ready access to the material, although Commission staff may review the material placed in each station's online public file, just as Commission staff currently reviews station public files to determine compliance with Commission rules.

104. *Working Group and Pilot Program.* We decline to adopt NAB's proposal that the Commission create a joint Commission-broadcaster working group or a pilot program to address the implementation issues and technical challenges raised by the online public file. NAB argues that a working group, through which the Commission would work with broadcasters to design the online public file and develop rules for its use, would likely reduce overall costs and burdens for the Commission and stations by identifying more quickly potential problems and their solutions. NAB and others also support a pilot program, through which a limited number of stations would test the online public file before the Commission requires broadcast stations to post files to it. Named State Broadcasters Association argues that a pilot program is an important way for the Commission to meet its statutory obligations under the Paperwork Reduction Act. We disagree with their argument that rules implementing the Paperwork Reduction Act require the Commission to test information collections a pilot program. These commenters argue that the Commission will gain valuable experience and insight if it conducts a pilot program involving the licensees of representative large, medium, and small market commercial and noncommercial educational television stations, and their trade association representatives. Other implementation suggestions include transition periods, phase-in approaches, and workshops.

105. For more than ten years the Commission has been exploring in this proceeding the best way to move broadcasters' public files online to make them more accessible. A broad group of commercial and noncommercial broadcasters has participated in every phase of the proceeding. We do not believe a working group or pilot program is necessary to ensure that the process of implementing an online public file is successful, and we believe that the creation of a working group as a condition precedent could unduly delay its implementation. One commenter claims that details of a ''pilot program'' were not properly raised in the *FNPRM.* To the extent these notice concerns relate to the phase-in approach we are adopting in this proceeding, we note that in the *FNPRM,* the Commission sought comment on whether we should ''consider creating different requirements for small television broadcasters.'' In any event, the Commission has discretion to implement changes in a step-by-step fashion.

106. We are addressing the concerns expressed about implementation, however. The Commission is undertaking rigorous testing of the online public file to ensure a smooth user experience. We will provide opportunities for user testing and education before stations are required to upload their online public files. Because our rules will require stations simply to upload information to a Commission-hosted online public file, a process similar to uploading applications to CDBS—which licensees have been

[10] As required by the Federal Records Act, 44 U.S.C. 3301, *et seq.,* the Commission will create a records schedule to set the retention and disposal of the files. The schedule will require approval by the National Archives and Records Administration. The records schedule will govern our handling of the station files.

doing for more than ten years—we do not believe that this process demands the kind of groundwork that broadcasters advocate. As already discussed, only 200 stations, or approximately 11% of all stations, will be required to upload their political files for the first two years. While this is not a pilot program, we believe that this smaller group of stations, which as major-network affiliates are generally likely to be relatively capable and sophisticated users of technology, can assist in meeting NAB's stated goals of addressing implementation issues and technical challenges as they arise. In addition, as discussed above, we believe that the user testing and education we will provide will assist stations with any concerns they may have. Commission staff will be dedicated to assisting stations with any issues they may confront after implementation of the online public file. We will also explore the option of providing user or peer support groups to help stations identify and work through implementation issues. Such support groups can assist the Commission in identifying whether any issues are common to many users, or station-specific.

F. Announcements and Links

107. We decline to adopt the *FNPRM's* proposal to require stations to make on-air announcements about the availability of the online public file, but do adopt the proposal that stations provide information about the online public file on their Web sites to the extent that they have them. In the *2007 Report and Order,* the Commission adopted a requirement that stations make twice-daily announcements about the online availability of the public file. On reconsideration, public television petitioners argued that this was unduly burdensome, and asked that the Commission reduce this requirement to a few times a week, at most. In the *FNPRM,* the Commission proposed that stations be required to notify viewers of the existence, location, and accessibility of a station's public file; it noted that if most viewers are unaware of the existence of the public file or how to access it, its usefulness would be greatly diminished.

108. The Commission has long required stations to identify both the call letters of their stations and the cities which they are primarily licensed to serve in order to enable the public to readily ''identify the stations to which they are listening and, further, to identify the communities which they are primarily licensed to serve.'' APTS and PBS argue that stations should have the option of making announcements regarding the online public file on their Web sites without having to also make an on-air announcement. APTS and PBS argue that on-air announcements are ineffective in informing the public because they are fleeting and might not reach all individuals within the community, whereas a notice on the station's Web site is more likely to be found by persons who are interested in accessing an online public file and can provide more detail. We are persuaded that providing information on a station's Web site about the existence and location of the online public file is a better means of ensuring that all viewers know about the availability of the online public file than requiring occasional on-air announcements. Stations will, however be required to revise their on-air pre- and post-filing renewal announcements to reflect the availability of a station's renewal application on the Commission's Web site, as reflected in Appendix A of the *Second Report and Order.*

109. We adopt the tentative conclusion that stations that have Web sites be required to place a link to the online public file on their home page. Common Frequency supports the proposal, and no commenter opposed it. Although we have concluded that posting station information to an online public file hosted by the Commission will make the information easily accessible by viewers, we want to ensure that those viewers who seek such information on a station's Web site are directed to the online public file, particularly since stations will not be required to broadcast on-air announcements regarding the change in location of their public file. In lieu of requiring stations to announce on their Web sites the availability of their correspondence files at their main studios, we will include language in the online public file that directs the public to the station's main studio to access letters and email from the public.

110. We also adopt the *FNPRM's* proposed requirement that stations that have Web sites include on their home page contact information for a station representative that can assist any person with disabilities with issues related to the content of the public files. We note that if stations receive comments about the accessibility of the online public file system, it should direct those questions and concerns to the Commission. PIPAC noted that for a person with disabilities, ''the burden of searching through several pages or levels becomes an insurmountable barrier.'' We will adopt the proposal, which no commenter opposed.

G. Radio and Multichannel Video Programming Distributors

111. Consistent with the *FNPRM,* we limit this proceeding to television stations at this time. In the *FNPRM,* the Commission noted that this proceeding is directed toward television broadcasters, and that we may require radio licensees to abide by similar public file reforms at a later date. LUC Media Group asks that the Commission consider requiring radio and cable systems to also maintain an online public file. We disagree that we should extend the online public file rules to radio and cable systems (or other multichannel video programming distributors (''MVPDs'')) at this time. First, because this proceeding has long focused only on television stations, we do not have a sufficient record concerning radio stations or MVPDs on which to consider possible new rules for those entities. Second, as discussed in the *FNPRM,* we anticipate that starting the online public file process with the much smaller number of television licensees, rather than with all broadcasters and MVPDs, will ease the initial implementation of the online public file.[11]

112. Public TV Licensees asks that we allow NCE radio stations, or at least those that are licensed to the same entity as, or under common control with, an NCE television station, to maintain their public inspection files online on the Commission's Web site on a voluntary basis. Public Television Licensees argues that this will allow radio stations that are jointly owned or operated with television stations to avoid duplicative efforts from having to maintain two separate public file systems, involving some of the same documents. It notes that with respect to the NCE rules, all of the requirements for radio stations are being included in the proposed online public file. We appreciate that commonly owned and operated radio stations may prefer an

[11] We reject arguments that requiring television broadcasters to place their political files online will put them at a disadvantage with respect to competitors, such as MVPDs and radio stations. As discussed above, to the extent competitors and potential advertisers have an economic incentive to access this information, they can already do so at the station; the online disclosure rule will not alter the economic incentives of these entities in any meaningful way. In any event, the Commission has discretion to implement changes in a multistep fashion. We further note that 75% of political advertising is spent on broadcast television, thus demonstrating a preference by media buyers to utilize broadcast television over other forms of available media to reach voters or customers. There is no evidence in the record to suggest that such advertising would shift to other forms of media simply because rate information, already public, will now be accessible online.

early transition to the online public file. In this initial phase of implementing the online public file, however, we are concerned about adding a significant number of additional entities to the universe of users. As we and the broadcasting industry gain more experience with the online public file we will revisit the possibility of allowing stations not required to use the online public file to use it on a voluntary basis. We delegate to Commission staff the authority to allow (but not require) radio stations to voluntarily post their public files at such time as staff determines that such an option is feasible and desirable; this will ensure that radio stations wishing to avail themselves of the online public file can do so promptly. We further authorize Commission staff to take into account common-ownership considerations if appropriate.

IV. Procedural Matters

A. Regulatory Flexibility Analysis

113. As required by the Regulatory Flexibility Act (''RFA''), an Initial Regulatory Flexibility Analysis (''IRFA'') was incorporated in the *Order on Reconsideration and Further Notice of Proposed Rulemaking* (*Further Notice*) in MB Docket 00–168. The Commission sought written public comment on the proposals in the *Further Notice,* including comment on the IRFA. We received comments from the North Carolina Association of Broadcasters *et al.* specifically directed toward the IRFA. These comments are discussed below. This Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

Need for, and Objectives of, the Second Report and Order

114. One of a television broadcaster's fundamental public interest obligations is to air programming responsive to the needs and interests of its community of license. Broadcasters are afforded considerable flexibility in how they meet that obligation. Among other things, they are required to maintain a public inspection file, which gives the public access to information about the station's operations. The goal of this *Second Report and Order* is to modernize this public inspection file requirement, making the public file information more accessible to members of the public who cannot visit a station during business hours to review the public file.

115. The *Second Report and Order* adopts rule changes that will:

- Replace the requirement that television stations maintain a paper public file at their main studios with a requirement to submit documents for inclusion in an online public file, including the political file, to be hosted by the Commission;
- Reduce the number of documents that television stations would be required to upload to an online public file, by automatically linking to information already collected by the Commission;
- Streamline the information required to be kept in the online file, such as by excluding letters and emails from the public; and
- Give the online public file a uniform organizational structure to allow consumers to more easily navigate the public files.

Legal Basis

116. The proposed action is authorized pursuant to Sections 1, 2, 4(i), 303, and 405 of the Communications Act, 47 U.S.C. 151, 152, 154(i), 303, and 405.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA

117. In the IRFA, we stated that our purpose was to ensure that any changes to applicable rules would impose only minimal adverse impact on small entities. We also solicited comments on alternatives to the proposed rules that would minimize the impact that any changes to our rules might have on small entities. In their comments, North Carolina Association of Broadcasters *et al.* states that the IRFA has not ''fully acknowledged, much less actually considered and developed any data to evaluate, the economic impacts of its proposals to require broadcasters to upload their political files to the FCC's servers and to require broadcasters to report all sponsorship identifications in the online public file.'' The North Carolina Association of Broadcasters *et al.* also states that ''the Commission has underestimated the burden of creating, updating, and maintaining these materials'', and has not analyzed the costs to the Commission, which it claims will ''undoubtedly'' be bourn by small businesses via increased regulatory fees.

118. We disagree with these claims. The *FNPRM* and *Second Report and Order,* including the IRFA and this FRFA, consider the impacts of this revised recordkeeping requirement. Section III.B. of the *Second Report and Order* discusses how broadcasters' initial costs of compliance are minimized, and how the online public file will ultimately lead to cost savings. This section discusses the Commission's cost analysis, including our determination that broadcaster's initial costs of compliance to upload their existing public file will average from $80 to $400 per station. We understand that North Carolina Association of Broadcasters *et al.* disagrees with our evaluation of the burdens that will be placed upon broadcasters in order to comply with these revised recordkeeping requirements as discussed in the *FNPRM.* Those arguments are considered in this *Second Report and Order.* We also disagree with North Carolina Association of Broadcasters *et al.'s* assertion that this Regulatory Flexibility Analysis must more fully consider costs to the Commission. We find that such a claim by the Association is based on purely speculative, and therefore spurious, grounds. In making the determinations reflected in the *Second Report and Order,* we have considered the impact of our actions on small entities, which is the requirement of the Regulatory Flexibility Act. In any event, the Commission is taking steps in this *Second Report and Order* to minimize burdens on small entities, by undertaking the automatic posting of several items that are required to be placed in the online public file, as discussed in Section E, *supra.* In addition, the Commission declined to adopt the proposal that stations report all sponsorship identifications, as discussed by the North Carolina Association of Broadcasters, and shared services agreements, along with weekly on-air announcements. Also, the Commission is providing an exemption from uploading the political file to all stations that are not in the top 50 DMAs and all stations not affiliated with the top four national television broadcast networks, regardless of the size of the market they serve, until July 1, 2014. This will enable small market and non-affiliated broadcasters to have two additional years to familiarize themselves with the online filing requirements before they need to begin uploading their political files on a going-forward basis.

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

119. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term

''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. Below, we provide a description of such small entities, as well as an estimate of the number of such small entities, where feasible.

120. *Television Broadcasting.* The SBA defines a television broadcasting station as a small business if such station has no more than $14.0 million in annual receipts. Business concerns included in this industry are those ''primarily engaged in broadcasting images together with sound.'' The Commission has estimated the number of licensed commercial television stations to be 1,390. According to Commission staff review of the BIA Kelsey Inc. Media Access Pro Television Database (BIA) as of January 31, 2011, 1,006 (or about 78 percent) of an estimated 1,298 commercial television stations in the United States have revenues of $14 million or less and, thus, qualify as small entities under the SBA definition. The Commission has estimated the number of licensed noncommercial educational (''NCE'') television stations to be 391. We note, however, that, in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. The Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

121. In addition, an element of the definition of ''small business'' is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply do not exclude any television station from the definition of a small business on this basis and are therefore over-inclusive to that extent. Also, as noted, an additional element of the definition of ''small business'' is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities and our estimates of small businesses to which they apply may be over-inclusive to this extent.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

122. The rule changes adopted in the *Second Report and Order* affect reporting, recordkeeping, or other compliance requirements. Television broadcasters are currently required to maintain a copy of their public inspection files at their main studios. The *Second Report and Order* requires stations to replace that requirement with a requirement to submit documents for inclusion in an online public file, including the political file, to be hosted on the Commission's Web site. Items in the public file that must also be filed with the Commission, including FCC authorizations, applications and related materials, contour maps, ownership reports and related materials, portions of the equal employment opportunity file, the public and broadcasting manual, children's television programming reports (Form 398), and DTV transition education reports (Form 388), will be automatically imported into the station's online public file. Television stations will only be responsible for uploading and maintaining items that are not required to be filed with the Commission under any other rule. The *Second Report and Order* also excludes some items from the online public file requirement, such as the existing political file and letters and emails from the public, which will continue to be maintained at the station, and also declines to add other items to the online public file requirement, including sponsorship identifications and shared services agreements, and weekly announcements of the existence of the public file.

Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

123. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

124. The *Second Report and Order* seeks to minimize and modernize reporting requirements on all television broadcasters, by having the Commission host the online public file. The previous *Report and Order* in this proceeding, which has been vacated, required stations to host their own public file. Having the Commission host the public file will ease the administrative burdens on all broadcasters. More than one-third of the required contents of the public file already have to be filed with the Commission, and the *Second Report and Order* requires the Commission to import and update that information, creating efficiencies for broadcasters. North Carolina Association of Broadcasters *et al.* note that the estimate for the proportion of the public file that is already filed with the Commission is based on categories of filings, and not the overall amount of paperwork that needs to be filed.

125. Given the wide variations of most public files, we are not able to estimate the precise decrease in burdens that each station will undergo by no longer being responsible for placing in the public file items that are already filed by the Commission. But regardless whether the decrease in burdens is measured by category or by overall amount of paperwork, every station will have its burdens reduced by eliminating this duplicative requirement. We also understand that all stations will have an increased burden for the initial transition period from the paper public file to an online public file. We do not believe that this effort will be unduly burdensome on small entities, and we believe that any such burdens are trumped by the increased efficiencies that will result from such a transition.

126. In any event, the *Second Report and Order* does not require any station to upload its existing political files, instead allowing stations to retain such materials at the station until those files expire after their two year retention period. All stations will only be required to upload political file material on a going-forward basis. In addition, the Commission is exempting all stations that are not in the top 50 DMAs and all stations not affiliated with the top four national television broadcast networks, regardless of the size of the market they serve, from having to post new political file materials online until July 1, 2014 from including their political file material in the online public file. After that date, those stations will be required to upload new political file material on a going-forward basis. This will enable non-affiliated broadcasters and smaller market broadcasters to have additional time to

familiarize themselves with the online filing requirements before they need to begin uploading their political files.

127. Overall, in proposing rules governing an online public file requirement, we believe that we have appropriately balanced the interests of the public against the interests of the entities who will be subject to the rules, including those that are smaller entities.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

128. None.

B. Paperwork Reduction Act Analysis

129. This document contains proposed information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, will invite the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995.[12] The Commission previously sought comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 or fewer employees.

130. The Commission will send a copy of this *Second Report and Order* to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

V. Ordering Clauses

131. Accordingly, *It is ordered* that, pursuant to the authority contained in sections 1, 2, 4(i), 303, 307, and 315 of the Communications Act, 47 U.S.C. 151, 152, 154(i), 303, 307, 315, this *Second Report and Order* is adopted.

132. *It is further ordered* that the requirement that stations place their new public inspection file documents on the Commission-hosted online public file shall be effective 30 days after the Commission publishes a notice in the **Federal Register** announcing OMB approval. Stations will be responsible for placing existing public file documents into the Commission-hosted online public file, with the exception of letters and emails from the public and the existing political file, as required by this *Second Report and Order,* within six months after the Commission publishes a notice in the **Federal Register** announcing OMB approval. Until July 1, 2014, stations not in the top 50 DMAs and all stations not affiliated with the top four networks, regardless of the size of the market they serve, are exempt from the requirement, under 47 CFR 73.3526(b)(3) and 73.3527(b)(3), of filing their political file online.

133. *It is further ordered* that the proceeding in MM Docket No. 00–44 is terminated.

134. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this *Second Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

For the reasons stated in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The Authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 307, and 554.

■ 2. Amend § 73.1212 by revising paragraph (e) to read as follows:

§ 73.1212 Sponsorship identification; list retention; related requirements.

* * * * *

(e) The announcement required by this section shall, in addition to stating the fact that the broadcast matter was sponsored, paid for or furnished, fully and fairly disclose the true identity of the person or persons, or corporation, committee, association or other unincorporated group, or other entity by whom or on whose behalf such payment is made or promised, or from whom or on whose behalf such services or other valuable consideration is received, or by whom the material or services referred to in paragraph (d) of this section are furnished. Where an agent or other person or entity contracts or otherwise makes arrangements with a station on behalf of another, and such fact is known or by the exercise of reasonable diligence, as specified in paragraph (b) of this section, could be known to the station, the announcement shall disclose the identity of the person or persons or entity on whose behalf such agent is acting instead of the name of such agent. Where the material broadcast is political matter or matter involving the discussion of a controversial issue of public importance and a corporation, committee, association or other unincorporated group, or other entity is paying for or furnishing the broadcast matter, the station shall, in addition to making the announcement required by this section, require that a list of the chief executive officers or members of the executive committee or of the board of directors of the corporation, committee, association or other unincorporated group, or other entity shall be made available for public inspection at the location specified under § 73.3526. If the broadcast is originated by a network, the list may, instead, be retained at the headquarters office of the network or at the location where the originating station maintains its public inspection file under § 73.3526. Such lists shall be kept and made available for a period of two years.

* * * * *

■ 3. Amend § 73.1943 by adding paragraph (d) to read as follows:

§ 73.1943 Political file.

* * * * *

(d) *Location of the file.* A television station licensee or applicant must post all of the contents added to its political file after the effective date of this paragraph in the political file component of its public file on the Commission's Web site. A television station must retain in its political file maintained at the station, at the location specified in §§ 73.3526(b) or 73.3527(b), all material required to be included in the political file and added to the file prior to the effective date of this paragraph. The online political file must be updated in the same manner as paragraph (c) of this section.

■ 4. Amend § 73.3526 by revising paragraph (b) to read as follows:

§ 73.3526 Local public inspection file of commercial stations.

* * * * *

(b) *Location of the file.* The public inspection file shall be located as follows:

(1) For radio licensees, a hard copy of the public inspection file shall be maintained at the main studio of the station. For television licensees, letters and emails from the public, as required by paragraph (e)(9) of this section, shall be maintained at the main studio of the station. An applicant for a new station or change of community shall maintain its file at an accessible place in the

[12] Public Law 104–13. The Commission previously sought comment on these proposals. *See* 76 FR 72144 (Nov. 22, 2011).

proposed community of license or at its proposed main studio.

(2) A television station licensee or applicant shall place the contents required by paragraph (e) of this section of its public inspection file on the Commission's Web site, with the exception of letters and emails from the public as required by paragraph (e)(9) of this section, which shall be retained at the station in the manner discussed in paragraph (b)(1) of this section; and the political file as required by paragraph (e)(6) of this section, as discussed in paragraph (b)(3) of this section. A station must provide a link to the public inspection file hosted on the Commission's Web site from the home page of its own Web site, if the station has a Web site, and provide contact information on its Web site for a station representative that can assist any person with disabilities with issues related to the content of the public files. A station also is required to include in the online public file the station's main studio address and telephone number, and the email address of the station's designated contact for questions about the public file. To the extent this section refers to the local public inspection file, it refers to the public file of an individual station, which is either maintained at the station or on the Commission's Web site, depending upon where the documents are required to be maintained under the Commission's rules.

(3) A television station licensee or applicant shall place the contents required by paragraph (e)(6) of this section of its political inspection file on the Commission's Web site. Political inspection file material in existence 30 days after the effective date of this provision shall continue to be retained at the station in the manner discussed in paragraph (b)(1) of this section until the end of its retention period. Any station not in the top 50 DMAs, and any station not affiliated with one of the top four broadcast networks, regardless of the size of the market it serves, shall continue to retain the political file at the station in the manner discussed in paragraph (b)(1) of this section until July 1, 2014. For these stations, effective July 1, 2014, any new political file material shall be placed on the Commission's Web site, while the material in the political file as of July 1, 2014, if not placed on the Commission's Web site, shall continue to be retained at the station in the manner discussed in paragraph (b)(1) of this section until the end of its retention period. However, any station that is not required to place its political file on the Commission's Web site before July 1, 2014 may choose to do so, instead of retaining the political file at the station in the manner discussed in paragraph (b)(1) of this section.

(4) The Commission will automatically link the following items to the electronic version of all licensee and applicant public inspection files, to the extent that the Commission has these items electronically: authorizations, applications, contour maps; ownership reports and related materials; portions of the Equal Employment Opportunity file held by the Commission; ''The Public and Broadcasting''; Letters of Inquiry and other investigative information requests from the Commission, unless otherwise directed by the inquiry itself; Children's television programming reports; and DTV transition education reports. In the event that the online public file does not reflect such required information, the licensee will be responsible for posting such material.

* * * * *

■ 5. Amend § 73.3527 by revising paragraph (b) to read as follows:

§ 73.3527 Local public inspection file of noncommercial educational stations.

* * * * *

(b) *Location of the file.* The public inspection file shall be located as follows:

(1) For radio licensees, a hard copy of the public inspection file shall be maintained at the main studio of the station. An applicant for a new station or change of community shall maintain its file at an accessible place in the proposed community of license or at its proposed main studio.

(2) A noncommercial educational television station licensee or applicant shall place the contents required by paragraph (e) of this section of its public inspection file on the Commission's Web site, with the exception of the political file as required by paragraph (e)(5) of this section, which may be retained at the station in the manner discussed in paragraph (b)(1) of this section until July 1, 2014. Effective July 1, 2014, any new political file material shall be placed on the Commission's Web site, while the material in the political file as of July 1, 2014, if not placed on the Commission's Web site, shall continue to be retained at the station in the manner discussed in paragraph (b)(1) of this section until the end of its retention period. However, any noncommercial educational station that is not required to place its political file on the Commission's Web site before July 1, 2014 may choose to do so instead of retaining the political file at the station in the manner discussed in paragraph (b)(1) of this section. A station must provide a link to the public inspection file hosted on the Commission's Web site from the home page of its own Web site, if the station has a Web site, and provide contact information for a station representative on its Web site that can assist any person with disabilities with issues related to the content of the public files. A station also is required to include in the online public file the station's main studio address and telephone number, and the email address of the station's designated contact for questions about the public file. To the extent this section refers to the local public inspection file, it refers to the public file of an individual station, which is either maintained at the station or on the Commission's Web site, depending upon where the documents are required to be maintained under the Commission's rules.

(3) The Commission will automatically link the following items to the electronic version of all licensee and applicant public inspection files, to the extent that the Commission has these items electronically: Authorizations; applications; contour maps; ownership reports and related materials; portions of the Equal Employment Opportunity file held by the Commission; and ''The Public and Broadcasting''.

* * * * *

■ 6. Amend § 73.3580 by revising paragraphs (d)(4)(i) introductory text and script and (d)(4)(ii) introductory text and script to read as follows:

§ 73.3580 Local public notice of filing of broadcast applications.

* * * * *

(d) * * *

(4) * * *

(i) *Pre-filing announcements.* During the period and beginning on the first day of the sixth calendar month prior to the expiration of the license, and continuing to the date on which the application is filed, the following announcement shall be broadcast on the 1st and 16th day of each calendar month. Stations broadcasting primarily in a foreign language should broadcast the announcements in that language.

Radio announcement: On (*date of last renewal grant*) (*Station's call letters*) was granted a license by the Federal Communications Commission to serve the public interest as a public trustee until (*expiration date*).

Our license will expire on (*date*). We must file an application for renewal with the FCC (*date four calendar months prior to expiration date*). When filed, a copy of this application will be

available for public inspection during our regular business hours. It contains information concerning this station's performance during the last (*period of time covered by the application*). Individuals who wish to advise the FCC of facts relating to our renewal application and to whether this station has operated in the public interest should file comments and petitions with the FCC by (*date first day of last full calendar month prior to the month of expiration*).

Further information concerning the FCC's broadcast license renewal process is available at (*address of location of the station's public inspection file*) or may be obtained from the FCC, Washington, DC 20554.

Television announcement: On (*date of last renewal grant*) (*Station's call letters*) was granted a license by the Federal Communications Commission to serve the public interest as a public trustee until (*expiration date*).

Our license will expire on (*date*). We must file an application for renewal with the FCC (*date four calendar months prior to expiration date*). When filed, a copy of this application will be available for public inspection at *www.fcc.gov.* It contains information concerning this station's performance during the last (*period of time covered by the application*).

Individuals who wish to advise the FCC of facts relating to our renewal application and to whether this station has operated in the public interest should file comments and petitions with the FCC by (*date first day of last full calendar month prior to the month of expiration*).

Further information concerning the FCC's broadcast license renewal process is available at (*address of location of the station*) or may be obtained from the FCC, Washington, DC 20554.

* * * * *

(ii) *Post-filing announcements.* During the period beginning on the date on which the renewal application is filed to the sixteenth day of the next to last full calendar month prior to the expiration of the license, all applications for renewal of broadcast station licenses shall broadcast the following announcement on the 1st and 16th day of each calendar month. Stations broadcasting primarily in a foreign language should broadcast the announcements in that language.

Television announcement: On (*date of last renewal grant*) (*Station's call letters*) was granted a license by the Federal Communications Commission to serve the public interest as a public trustee until (*expiration date*).

Our license will expire on (*date*). We have filed an application for renewal with the FCC.

A copy of this application is available for public inspection at *www.fcc.gov.* It contains information concerning this station's performance during the last (*period of time covered by application*).

Individuals who wish to advise the FCC of facts relating to our renewal application and to whether this station has operated in the public interest should file comments and petitions with the FCC by (*date first day of last full calendar month prior to the month of expiration*).

Further information concerning the FCC's broadcast license renewal process is available at (*address of location of the station*) or may be obtained from the FCC, Washington, DC 20554.

Radio announcement: On (*date of last renewal grant*) (*Station's call letters*) was granted a license by the Federal Communications Commission to serve the public interest as a public trustee until (*expiration date*).

Our license will expire on (*date*). We have filed an application for renewal with the FCC.

A copy of this application is available for public inspection during our regular business hours. It contains information concerning this station's performance during the last (*period of time covered by application*).

Individuals who wish to advise the FCC of facts relating to our renewal application and to whether this station has operated in the public interest should file comments and petitions with the FCC by (*date first day of last full calendar month prior to the month of expiration*).

Further information concerning the FCC's broadcast license renewal process is available at (*address of location of the station's public inspection file*) or may be obtained from the FCC, Washington, DC 20554.

* * * * *

[FR Doc. 2012–11065 Filed 5–10–12; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 77, No. 92
Friday, May 11, 2012

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

[Docket No. FCIC–12–0001]

RIN 0563–AC37

Common Crop Insurance Regulations; Processing Sweet Corn Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to amend the Common Crop Insurance Regulations, Processing Sweet Corn Crop Insurance Provisions. The intended effect of this action is to provide policy changes that better meet the needs of insured producers. The proposed changes will be effective for the 2013 and succeeding crop years.

DATES: Written comments and opinions on this proposed rule will be accepted until close of business June 11, 2012 and will be considered when the rule is to be made final.

ADDRESSES: FCIC prefers that comments be submitted electronically through the Federal eRulemaking Portal. You may submit comments, identified by Docket ID No. FCIC–12–0001, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Director, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, P.O. Box 419205, Kansas City, MO 64133–6205.

All comments received, including those received by mail, will be posted without change to *http://www.regulations.gov*, including any personal information provided, and can be accessed by the public. All comments must include the agency name and docket number or Regulatory Information Number (RIN) for this rule. For detailed instructions on submitting comments and additional information, see *http://www.regulations.gov*. If you are submitting comments electronically through the Federal eRulemaking Portal and want to attach a document, we ask that it be in a text-based format. If you want to attach a document that is a scanned Adobe PDF file, it must be scanned as text and not as an image, thus allowing FCIC to search and copy certain portions of your submissions. For questions regarding attaching a document that is a scanned Adobe PDF file, please contact the RMA Web Content Team at (816) 823–4694 or by email at *rmaweb.content@rma.usda.gov.*

Privacy Act: Anyone is able to search the electronic form of all comments received for any dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the complete User Notice and Privacy Notice for Regulations.gov at *http://www.regulations.gov/#!privacyNotice.*

FOR FURTHER INFORMATION CONTACT: Tim Hoffmann, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, P.O. Box 419205, Stop 0812, Room 421, Kansas City, MO 64141–6205, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be non-significant for the purposes of Executive Order 12866 and, therefore, it has not been reviewed by the OMB.

Paperwork Reduction Act of 1995

Pursuant to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collections of information in this rule have been approved by OMB under control number 0563–0053.

E-Government Act Compliance

FCIC is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 13132

It has been determined under section 1(a) of Executive Order 13132, Federalism, that this rule does not have sufficient implications to warrant consultation with the States. The provisions contained in this rule will not have a substantial direct effect on States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Regulatory Flexibility Act

FCIC certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Program requirements for the Federal crop insurance program are the same for all producers regardless of the size of their farming operation. For instance, all producers are required to submit an application and acreage report to establish their insurance guarantees and compute premium amounts, and all producers are required to submit a notice of loss and production information to determine the amount of an indemnity payment in the event of an insured cause of crop loss. Whether a producer has 10 acres or 1000 acres, there is no difference in the kind of information collected. To ensure crop insurance is available to small

entities, the Federal Crop Insurance Act authorizes FCIC to waive collection of administrative fees from limited resource farmers. FCIC believes this waiver helps to ensure that small entities are given the same opportunities as large entities to manage their risks through the use of crop insurance. A Regulatory Flexibility Analysis has not been prepared since this regulation does not have an impact on small entities, and, therefore, this regulation is exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605).

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This proposed rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. With respect to any direct action taken by FCIC or to require the insurance provider to take specific action under the terms of the crop insurance policy, the administrative appeal provisions published at 7 CFR part 11 or 7 CFR part 400, subpart J for the informal administrative review process of good farming practices as applicable, must be exhausted before any action against FCIC may be brought.

Executive Order 12988

This final rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. With respect to any direct action taken by FCIC or action by FCIC directing the insurance provider to take specific action under the terms of the crop insurance policy, the administrative appeal provisions published at 7 CFR part 11, or 7 CFR part 400, subpart J for determinations of good farming practices, as applicable, must be exhausted before any action against FCIC for judicial review may be brought.

Environmental Evaluation

This action is not expected to have a significant economic impact on the quality of the human environment, health, or safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Background

FCIC proposes to amend the Common Crop Insurance Regulations (7 CFR part 457) by revising § 457.154, Processing Sweet Corn Crop Insurance Provisions, to be effective for the 2013 and succeeding crop years. Several requests have been made for changes to improve the insurance coverage offered and to better meet the needs of insured producers. Because of limited availability of price data from third party sources (e.g., Agricultural Marketing Service) for sweet corn grown under contract with a processor, the insurance guarantee provided by the sweet corn program is currently based on estimated price elections that may vary significantly from actual prices offered by processors. In evaluating the use of processor contracts for crops that require a contract as a condition of insurability, it was found that the base contract price more accurately reflects the value of processing sweet corn. As such, FCIC is proposing to amend the Processing Sweet Corn Crop Insurance Provisions to utilize the base contract price as the price election, for the purpose of establishing a more accurate insurance guarantee that reflects the expected market price for processing sweet corn.

The proposed changes are as follows:

1. Section 1—FCIC proposes to add the definition of ''Price election'' utilizing the base contract price as the price election, for the purpose of establishing a more accurate insurance guarantee that reflects the expected market price for processing sweet corn.

Accordingly, as set forth in the preamble, the Federal Crop Insurance Corporation proposes to amend 7 CFR part 457 effective for the 2013 and succeeding crop years as follows:

PART 457—COMMON CROP INSURANCE REGULATIONS

1. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(o).

2. Amend § 457.154 by:

a. Removing ''1998'' from the introductory text and adding ''2013'' in its place;

b. Adding the definition of ''price election'' in section 1.''

The added text reads as follows:

§ 457.154 Processing Sweet Corn crop insurance provisions.

* * * * *

1. Definitions.

* * * * *

Price election. In lieu of the definition of price election in the Basic Provisions, the price election will be the base contract price stated in your processor contract.

* * * * *

Signed in Washington, DC, on May 3, 2012.

William J. Murphy,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 2012–11373 Filed 5–10–12; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0503; Directorate Identifier 2011–SW–032–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Eurocopter Deutschland GmbH (ECD) Model BO–105A, BO–105C, and BO–105S helicopters. This proposed AD is prompted by initial findings from an accident investigation of an ECD Model BO 105 helicopter which indicated deterioration of the main gearbox (MGB) caused by a contaminated oil supply. The proposed actions are intended to detect oil contamination in the MGB, which if not detected, could result in MGB deterioration, MGB failure, and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by July 10, 2012.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket

Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

• *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052, telephone (972) 641–0000 or (800) 232–0323, fax (972) 641–3775, or at *http://www.eurocopter.com/techpub.* You may review copies of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Rao Edupuganti, Aerospace Engineer, FAA, Rotorcraft Directorate, Regulations and Policy Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5110, email *rao.edupuganti@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued AD No.: 2011–0091, dated May 18, 2011 (AD 2011–0091), which supersedes EASA AD No.: 2010–0223, dated October 26, 2010 (AD 2010–0223), to correct an unsafe condition for all ECD BO105 A, BO105 C, BO105 D, and BO105 S helicopters. EASA advises that in 2010, an accident occurred with a BO105 helicopter and the initial findings indicated that ''the event was linked with'' a deterioration of the MGB due to a contaminated oil supply. EASA states this condition, if not detected, could lead to MGB failure and consequent loss of control of the helicopter.

FAA's Determination

These helicopters have been approved by the aviation authority of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with Germany, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other helicopters of the same type design.

Related Service Information

ECD issued Alert Service Bulletin (ASB) BO105–10–125, dated September 2, 2010 (BO105–10–125), which specifies a one-time inspection of the MGB magnetic plug/chip detector (magnetic plug) and oil filter, and revised criteria for the corrective action to be taken as a result of the inspection. EASA issued AD 2010–0223, mandating the requirements of BO105–10–125 and applying the revised criteria to future MGB magnetic plug inspections.

Since that AD was issued, it was determined that repetitive inspections of the magnetic plug and oil filter are necessary. ECD revised the ASB and issued ASB BO105–10–125, Revision 1, dated April 4, 2001 (BO105–10–125R1), which retains the requirements of BO105–10–125 and requires an inspection of the magnetic plug every 10 flight hours and an inspection of the oil filter every 100 flight hours. EASA classified this ASB as mandatory and issued AD 2011–0091, which supersedes AD 2010–0223.

Proposed AD Requirements

This proposed AD would require inspecting the MGB oil filter and MGB magnetic plug. If the MGB oil filter or MGB magnetic plug contains metallic fuzz, depending on the amount of metallic fuzz, this proposed AD would require cleaning the magnetic plug, flushing the main transmission, changing the oil, and performing a ground run. If the MGB oil filter or MGB magnetic plug contains a chip, this proposed AD would require replacing the main transmission with an airworthy main transmission, and cleaning the oil cooler and oil lines. This proposed AD would also require repeating the MGB magnetic plug inspection every 10 hours time-in-service (TIS), and repeating the MGB oil filter inspection every 100 hours TIS.

Differences Between This AD and the EASA AD

The EASA AD applies to Model BO105 D helicopters; the proposed AD does not as this model is not type certificated in the U.S.

Costs of Compliance

We estimate that this proposed AD would affect 97 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Inspecting and cleaning the magnetic plug and oil filter would require approximately 2 work-hours at an average labor rate of $85 per hour, for a total cost per inspection cycle of $170 per helicopter and a total cost to the U.S. operator fleet of $16,490. Flushing the main transmission, performing a ground run, and re-inspecting the MGB oil filter and magnetic plug would require approximately 4 work-hours at an average labor rate of $85 per hour, for a cost per helicopter of $340. Replacing the main transmission would require approximately 40 work-hours at an average labor rate of $85 per hour, and required parts would cost $225,000, for a total cost per helicopter of $228,400.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701:

General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new Airworthiness Directive (AD):

Eurocopter Deutschland GMBH: Docket No. FAA–2012–0503; Directorate Identifier 2011–SW–032–AD.

(a) Applicability

This AD applies to Model BO–105A, BO–105C, and BO–105S helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as deterioration of the main gearbox (MGB) caused by oil contamination. This condition could result in MGB failure and subsequent loss of control of the helicopter.

(c) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(d) Required Actions

(1) Within 100 hours time-in-service (TIS) or 3 months, or at the next scheduled MGB magnetic plug/chip detector (magnetic plug) inspection, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS, inspect the MGB oil filter for chips and the MGB magnetic plug for fine particles (magnetic fuzz) or chips. A ''chip'' is a solid piece of metal but not metallic fuzz.

(i) If there are no chips on the MGB oil filter or on the magnetic plug, and the metallic fuzz covers less than 25% of the magnetic plug, clean the magnetic plug.

(ii) If there are no chips on the MGB oil filter or on the magnetic plug, but the metallic fuzz covers 25% or more of the magnetic plug, flush the main transmission, change the oil, perform a ground run for 15 minutes at the flight-idle power setting, and then re-inspect the MGB oil filter and magnetic plug for a chip and the quantity of metallic fuzz on the metallic plug.

(iii) If there is a chip on the MGB oil filter or on the magnetic plug, or, after complying with paragraph (d)(1)(ii) of this AD, metallic fuzz covers 25% or more of the magnetic plug, replace the main transmission with an airworthy main transmission and clean the oil cooler and oil lines.

(2) At intervals not to exceed 10 hours TIS, inspect the magnetic plug for a chip or metallic fuzz in accordance with the requirements of paragraph (d)(1) of this AD.

(e) Alternative Methods of Compliance (AMOC)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Rao Edupuganti, Aerospace Engineer, FAA, Rotorcraft Directorate, Regulations and Policy Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5110, email *rao.edupuganti@faa.gov*.

(2) For operations conducted under a Part 119 operating certificate or under Part 91, Subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(f) Additional Information

(1) Eurocopter Alert Service Bulletin BO105–10–125, Revision 1, dated April 4, 2011, which is not incorporated by reference, contains additional information about the subject of this AD. You may review a copy of this information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2011–0091, dated May 18, 2011.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6320: Main Rotor Gearbox.

Issued in Fort Worth, Texas, on May 2, 2012.

Carlton N. Cochran,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–11468 Filed 5–10–12; 8:45 am][FR Doc. 2012–11468 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0500; Directorate Identifier 2010–SW–014–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Eurocopter Deutschland GmbH (ECD) model EC135 helicopters, except the EC 135 P2+ and T2+. This proposed AD was prompted by two reports of the plain journal bearings moving in relation to the main rotor swashplate sliding sleeve (sliding sleeve). The actions specified by this proposed AD are intended to detect shifting of the plain journal bearing, which could limit the movement of the collective control and result in subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by July 10, 2012.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov*. Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

• *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053–4005, telephone (800) 232–0323, fax (972) 641–3710, or at *http://www.eurocopter.com*. You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Gary Roach, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Regulations and Policy Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5130, email: *gary.b.roach@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued AD No. 2009–0272, dated December 18, 2009 (AD 2009–0272), to correct an unsafe condition for Eurocopter Model EC 135 and EC 635 helicopters. EASA advises that during two separate pre-flight checks on Model EC 135 helicopters in 2005, it was detected that one of the plain journal bearings of the sliding sleeve had moved to the outside of the sliding sleeve. EASA states that this condition, if not detected and corrected, could lead to a complete shift of the plain journal bearing to the inside or outside, creating the possibility of a limited movement of the collective, which could result in reduced control of the helicopter.

FAA's Determination

These helicopters have been approved by the aviation authority of the Federal Republic of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with the Federal Republic of Germany, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other helicopters of these same type designs.

Related Service Information

We reviewed Eurocopter Alert Service Bulletin (ASB) EC135–62A–021, dated June 23, 2005 (EC135–62A–021). EC135–62A–021 describes procedures for visually checking the upper and lower plain journal bearings of the sliding sleeve during preflight. EASA classified this ASB as mandatory and issued AD 2009–0272 to ensure the continued airworthiness of these helicopters.

Proposed AD Requirements

This proposed AD would require, at intervals not to exceed 5 hours time in service (TIS), visually inspecting the upper and lower plain journal bearings of the sliding sleeve to detect a dislocated plain journal bearing on Eurocopter Model EC 135 P1, P2, T1, and T2 helicopters with swashplate sliding sleeve, part number (P/N) L623M2006101, installed.

Differences Between This Proposed AD and the EASA AD

This proposed AD differs from the EASA AD as follows:

• This proposed AD requires the inspection to be performed by a mechanic, and repeated every 5 hours TIS. AD 2009–0272 allows the visual inspection to be accomplished by a pilot during preflight inspection.

• This proposed AD does not require contacting ECD customer service for corrective actions.

• This proposed AD provides terminating action for the inspection requirements for the upper and lower plain journal bearings by replacing the swashplate assembly with a later-design swashplate assembly, P/N L623M2005103.

• The EASA AD applies to ECD model EC635 aircraft, and this proposed AD does not because the EC635 does not have an FAA issued type-certificate.

Costs of Compliance

We estimate that this proposed AD would affect 218 helicopters of U.S. registry. We estimate that operators may incur the following costs in order to comply with this AD. Inspecting the upper and lower plain journal bearings requires about .25 work hour at an average labor rate of $85 per hour, for a cost per helicopter of $22 and a total cost to the U.S. operator fleet of $4,796 per inspection cycle. If required, replacing the swashplate assembly will require about 8 work hours at an average labor rate of $85 per hour, and required parts will cost about $38,586, for a total cost per helicopter of $39,266.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Eurocopter Deutschland GMBH: Docket No. FAA–2012–0500; Directorate Identifier 2010–SW–014–AD.

(a) Applicability

This AD applies to all Eurocopter Deutschland GmbH (ECD) Model EC135 helicopters, except EC 135 P2+ and EC135 T2+, with a swashplate assembly, part number (P/N) L623M2006101, installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as movement of the plain journal bearings to the outside of the main rotor swashplate sliding sleeve (sliding sleeve). This condition could limit movement of the collective and result in subsequent loss of control of the helicopter.

(c) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(d) Required Actions

Within 5 hours time-in-service (TIS), and thereafter at intervals not to exceed 5 hours TIS:

(1) Visually inspect the position of the upper plain journal bearings and determine if it is flush with the sliding sleeve.

Note 1: Figure 1 of Eurocopter Alert Service Bulletin EC135–62A–021, dated June 23, 2005, which is not incorporated by reference, contains additional information about the inspection.

(2) Visually inspect the lower plain journal bearing and determine if it is recessed 2 millimeters from the sliding sleeve.

(3) If the upper plain journal bearing is not flush with the sliding sleeve or the lower plain journal bearing is not recessed 2mm, before further flight, replace the swashplate assembly with an airworthy swashplate assembly.

(4) Replacing the swashplate assembly, P/N L623M2006101, with a later designed swashplate assembly, P/N L623M2005103, constitutes a terminating action for the requirements of this AD.

(e) Alternative Methods of Compliance (AMOC)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Gary Roach, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Regulations and Policy Group, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5130, email: *gary.b.roach@faa.gov.*

(2) For operations conducted under a Part 119 operating certificate or under Part 91, Subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(f) Additional Information

(1) Eurocopter Alert Service Bulletin EC135–62A–021, dated June 23, 2005, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, TX 75053–4005, telephone (800) 232–0323, fax (972) 641–3710, or at *http://www.eurocopter.com.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in European Aviation Safety Agency AD 2009–0272, dated December 18, 2009.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6230: Main Rotor Mast/Swashplate.

Issued in Fort Worth, Texas, on May 2, 2012.

Carlton N. Cochran,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–11470 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0502; Directorate Identifier 2010–SW–097–AD]

RIN 2120–AA64

Airworthiness Directives; Aeronautical Accessories, Inc. High Landing Gear Forward Crosstube Assembly

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Aeronautical Accessories, Inc. (AAI) high landing gear forward crosstube assemblies (crosstubes) installed on Agusta S.p.A. (Agusta) Model AB412 and AB412EP; and Bell Helicopter Textron, Inc. (Bell) Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters during production or based on a supplemental type certificate (STC). This proposed AD is prompted by two reports from the field of failed crosstubes. The proposed actions are intended to prevent failure of a crosstube, collapse of the landing gear, and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by July 10, 2012.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Aeronautical Accessories, Inc., P.O. Box 3689, Bristol, TN 37625–3689, telephone (423) 538–5151 or (800) 251–7094, fax (423) 538–8469, or at *http://www.aero-access.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Michael Kohner, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 222–5170; email *7-avs-asw-170@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We propose to adopt a new AD for AAI crosstubes, part number (P/N) 212–321–103, installed on Agusta Model AB412 and AB412EP helicopters, and Bell Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters, during production or under STC SR01052AT. This proposal would require creating a component history card or equivalent record, determining the total number of landings, and continuing recording the number of landings for each crosstube. This proposal would also require certain recurring visual, dimensional, and fluorescent penetrant inspections of each crosstube. This proposal would require repairing damaged crosstubes that are within acceptable limits. If there is a crack, or any corrosion or a nick, scratch, dent, or any other damage outside the maximum repair damage limits, this proposal requires, before further flight, replacing any unairworthy crosstube with an airworthy crosstube. This proposal is prompted by two reports from the field of failed crosstubes. This condition, if not corrected, could result in collapse of the landing gear, and subsequent loss of control of the helicopter.

FAA's Determination

We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information

We reviewed AAI Alert Service Bulletin (ASB) No. AA–08055, Revision B, dated August 12, 2009, which specifies establishing a takeoff/landing history, recurrent visual and fluorescent penetrant inspections of the crosstubes, and dimensional inspections of the skid gear. We have also reviewed AAI Instructions for Continued Airworthiness (ICA) for Crosstubes, Report No. AA–01136, Revision K, dated February 15, 2012, which contain the information necessary for inspection and maintenance of each crosstube installed on the Agusta and Bell helicopters.

Proposed AD Requirements

The proposed AD would require:

- Within 50 hours time-in-service (TIS), creating a component history card or equivalent record for each affected crosstube, and determining and recording the total number of landings. If the landing information is unavailable, estimating the number by multiplying the airframe hours TIS by a factor of 10. Continue to count and record the number of landings for each crosstube. For the purposes of this AD, a landing would be counted anytime the helicopter lifts off into the air and then lands again with any further reduction of the collective after the landing gear touches the ground.
- At specified intervals, using a 10X or higher magnifying glass and a strong light, inspecting each crosstube for a crack. If there is a crack, replacing the crosstube with an airworthy crosstube.
- At specified intervals, determining the horizontal deflection of each crosstube from the centerline of the helicopter (BL 0.0) to the outside of the skid tubes. If the crosstube measures outside the limits, replacing the crosstube with an airworthy crosstube.
- At specified intervals, removing each crosstube and performing a fluorescent penetrant inspection of each crosstube for a crack, any corrosion, a nick, scratch, dent, or any other damage. If there is a crack, replacing the crosstube with an airworthy crosstube. If there is any corrosion or a nick, scratch, dent, or any other damage repairing the crosstube to an airworthy configuration if the damage is within the maximum damage limits, or replacing with an airworthy crosstube.

Differences Between This Proposed AD and the Service Information

The service information uses the term ''flight hours.'' We use ''hours time-in-service.''

Costs of Compliance

We estimate that this proposed AD would affect 115 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD:

- Creating a historical record and determining the number of landings would require .5 work hour at an average labor rate of $85 per hour for a cost per helicopter of $42 and a cost to the U.S. operator fleet of $4,830 per inspection cycle.
- Preparing and inspecting the crosstube would require 8.5 work hours at an average labor rate of $85 per hour for a cost per helicopter of $722 and a cost to the U.S. operator fleet of $83,030 per inspection cycle.
- Performing the dimensional inspection of the skid gear would require 1 work hour at an average labor rate of $85 per hour for a cost per helicopter of $85 and a cost to the U.S. operator fleet of $9,775 per inspection cycle.
- Fluorescent penetrant inspecting the crosstube would require 24 work

hours at an average labor rate of $85 per hour for a cost per helicopter of $2,040 and a cost to the U.S. operator fleet of $234,600 per inspection cycle.

• If required, replacing a crosstube with an airworthy crosstube would require 10 work hours at an average labor rate of $85, required parts will cost $9,315, for a cost per helicopter of $10,165.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Aeronautical Accessories, Inc. (AAI): Docket No. FAA–2012–0502; Directorate Identifier 2010–SW–097–AD.

(a) Applicability

This AD applies to high landing gear forward crosstube assembly (crosstube), part number (P/N) 212–321–103, installed on Agusta S.p.A. Model AB412 and AB412EP and Bell Helicopter Textron, Inc. Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of the landing gear crosstube which could result in collapse of the landing gear and subsequent loss of control of the helicopter.

(c) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(d) Required Actions

(1) Within 50 hours time-in-service (TIS) after the effective date of this AD:

(i) Create a component history card or equivalent record for the crosstube by following the Accomplishment Instructions, Part A, paragraph 1., of AAI Alert Service Bulletin No. AA–08055, Revision B, dated August 12, 2009 (ASB).

(ii) Determine and record on the component history card or equivalent record the total number of landings for the crosstube. If the landing information is unavailable, estimate the number by multiplying the airframe hours TIS by 10. Continue to count and record the number of landings for the crosstube. For the purposes of this AD, a landing would be counted anytime the helicopter lifts off into the air and then lands again with any further reduction of the collective after the landing gear touches the ground.

(2) Within 50 hours TIS after the effective date of this AD or before reaching a total of 7,500 landings on any crosstube, whichever occurs later:

(i) Prepare the crosstube inspection areas as described in the Accomplishment Instructions, Part B, paragraphs 1. through 5. and Figure 1, of the ASB.

(ii) Using a 10X or higher power magnifying glass and a bright light, visually inspect the prepared areas of the crosstube for a crack. If there is a crack, before further flight, replace the crosstube with an airworthy crosstube.

(iii) If there is no crack, following the inspection, prime and paint the inspection areas by following the Accomplishment Instructions, Part B, paragraphs 7. and 8., of the ASB. If there is any corrosion or other damage, perform the replacement or repair required in paragraph (d)(5)(iv) of this AD before priming and painting the inspection areas.

(3) Thereafter, at intervals not to exceed 200 landings, clean the crosstube inspection areas by following the Accomplishment Instructions, Part C, paragraph 1., of the ASB. Using a 10X or higher power magnifying glass and a bright light, visually inspect the clear-coated areas of the crosstube for a crack. If there is a crack, before further flight, replace the crosstube with an airworthy crosstube.

(4) Within 30 days after the effective date of this AD or before reaching a total of 10,000 landings on any crosstube, whichever occurs later, and thereafter at intervals not to exceed 2,500 landings or 12 months, whichever occurs first, determine the horizontal deflection of the crosstube from the centerline of the helicopter (BL 0.0) to the outside of the skid tubes by following the Accomplishment Instructions, Part D, paragraphs 1. and 2., of the ASB. If the crosstube measures outside any of the limits depicted in Figure 2 of the ASB, before further flight, replace the crosstube with an airworthy crosstube.

(5) Within 3 months after the effective date of this AD or before reaching a total of 12,500 landings on any crosstube, whichever occurs later, and thereafter at intervals not to exceed 5,000 landings:

(i) Remove and disassemble the landing gear assembly and crosstube to prepare for a fluorescent penetrant inspection (FPI) by following the Accomplishment Instructions, Part E.1, paragraphs 1. through 6., of the ASB.

(ii) Clean and prepare the crosstube by removing the sealant and paint as described in the Accomplishment Instructions, Part E.2, paragraphs 1. through 3. and Figure 3, of the ASB.

(iii) Perform an FPI of the crosstube in the areas depicted in Figure 3 of the ASB for a crack, any corrosion, a nick, scratch, dent, or any other damage by following the Accomplishment Instructions, Part E.3, paragraph 1., of the ASB. If there is a crack, before further flight, replace the crosstube with an airworthy crosstube.

(iv) If there is any corrosion or a nick, scratch, dent, or any other damage, before further flight, repair the crosstube to an airworthy configuration if the damage is within the maximum repair damage limits or replace the crosstube with an airworthy crosstube. Chapter 3.5 Repair, Table 1. and Figure 3 of the AAI Instructions for

Continued Airworthiness for Crosstubes, Report No. AA–01136, Revision K, dated February 15, 2012, contains the maximum repair damage limits and repair procedures.

(e) Alternative Methods of Compliance (AMOC)

(1) The Manager, Rotorcraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Michael Kohner, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 222–5170; email *7-avs-asw-170@faa.gov*.

(2) For operations conducted under a Part 119 operating certificate or under Part 91, Subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(f) Additional Information

For service information identified in this AD, contact Aeronautical Accessories, Inc., P.O. Box 3689, Bristol, TN 37625–3689, telephone (423) 538–5151 or (800) 251–7094, fax (423) 538–8469, or at *http://www.aero-access.com.* You may review a copy of this information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 3213: Main Landing Gear Strut/Axle/Truck.

Issued in Fort Worth, Texas, on May 2, 2012.

Carlton N. Cochran,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–11472 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–1366; Airspace Docket No. 11–ANE–13]

Proposed Amendment of Class E Airspace; Bar Harbor, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E Airspace at Bar Harbor, ME, as the Surry Non-Directional Radio Beacon (NDB) has been decommissioned and new Standard Instrument Approach Procedures have been developed at Hancock County-Bar Harbor Airport. This action would enhance the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport. This action also would update the geographic coordinates of the airport.

DATES: Effective 0901 UTC, Comments must be received on or before June 25, 2012.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001; Telephone: 1–800–647–5527; Fax: 202–493–2251. You must identify the Docket Number FAA–2011–1366; Airspace Docket No. 11–ANE–13, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2011–1366; Airspace Docket No. 11–ANE–13) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2011–1366; Airspace Docket No. 11–ANE–13.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory circular No. 11–2A, Notice of Proposed Rulemaking distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace extending upward from 700 feet above the surface to support new Standard Instrument Approach Procedures developed at Hancock County-Bar Harbor Airport, Bar Harbor, ME. Airspace reconfiguration is necessary due to the decommissioning of the Surry NDB and cancellation of the NDB approach, and for continued safety and management of IFR operations at the airport. The geographic coordinates of the airport also would be adjusted to coincide with the FAAs aeronautical database.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9V, dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to

keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would amend Class E airspace at Hancock County-Bar Harbor Airport, Bar Harbor, ME.

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, effective September 15, 2011, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANE ME E5 Bar Harbor, ME [Amended]

Hancock County-Bar Harbor Airport, ME
(Lat. 44°26′59″ N., long. 68°21′42″ W.)

That airspace extending upward from 700 feet above the surface within a 7.4-mile radius of Hancock County-Bar Harbor Airport.

Issued in College Park, Georgia, on April 30, 2012.

Barry A. Knight,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2012–11404 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0301; Airspace Docket No. 12–AEA–3]

Proposed Revocation of Class E Airspace; Lloydsville, PA, and Proposed Amendment of Class D and E Airspace; Latrobe, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove the Class E Airspace listed at Lloydsville, PA, for Latrobe Hospital Heliport (old name), and incorporate Exela Health Latrobe Hospital Heliport (new name) into existing Class E airspace at Latrobe, PA. Also, this action proposes to amend Class D and E airspace at Latrobe, PA, as new Standard Instrument Approach Procedures have been developed at Arnold Palmer Regional Airport. The geographic coordinates for both the heliport and the airport would be updated. This action would enhance the safety and airspace management of Instrument Flight Rules (IFR) operations in the Latrobe, PA, area. This action also would recognize the airport name change to Arnold Palmer Regional Airport.

DATES: Comments must be received on or before June 25, 2012. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA, Order 7400.9 and publication of conforming amendments.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001; Telephone: 1–800–647–5527; Fax: 202–493–2251. You must identify the Docket Number FAA–2012–0301; Airspace Docket No. 12–AEA–3, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2012–0301; Airspace Docket No. 12–AEA–3) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov*.

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2012–0301; Airspace Docket No. 12–AEA–3.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory circular No. 11–2A, Notice of Proposed Rulemaking distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to remove the Class E airspace designation listed under LLoydsville, PA, for Latrobe Hospital Heliport, and incorporate Excela Health Latrobe Hospital Heliport, formerly Latrobe Hospital Heliport, into existing Class E airspace extending upward from 700 feet above the surface, at Latrobe, PA. Class D airspace, Class E surface airspace, and Class E airspace extending upward from 700 feet above the surface would be amended to support new standard instrument approach procedures at Arnold Palmer Regional Airport, Latrobe, PA, formerly Westmoreland County Airport. The geographic coordinates for the heliport and the airport also would be adjusted to coincide with the FAA's aeronautical database.

Class D and E airspace designations are published in Paragraphs 5000, 6004, and 6005, respectively, of FAA Order 7400.9V, dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in subtitle VII, part, A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would remove Class E airspace at Lloydsville, PA and amend Class D and E airspace in the Latrobe, PA, area.

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, effective September 15, 2011, is amended as follows:

* * * * *

Paragraph 5000 Class D Airspace.

* * * * *

AEA PA D Latrobe, PA [Amended]

Arnold Palmer Regional Airport, Latrobe, PA
(Lat. 40°16′29″ N., long. 79°24′24″ W.)

That airspace extending upward from the surface to and including 3,700 feet MSL within a 5-mile radius of Arnold Palmer Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E airspace designated as an extension to a Class D surface area.

* * * * *

AEA PA E4 Latrobe, PA [Amended]

Arnold Palmer Regional Airport, Latrobe, PA
(Lat. 40°16′29″ N., long. 79°24′24″ W.)

That airspace extending upward from the surface of Arnold Palmer Regional Airport within the 045° bearing from the airport clockwise to the 210° bearing, extending from the 5-mile radius of the airport to 10 miles southwest. This Class E airspace area shall be effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA PA E5 Lloydsville, PA [Removed]

AEA PA E5 Latrobe, PA [Amended]

Arnold Palmer Regional Airport, Latrobe, PA
(Lat. 40°16′2″ N., long. 79°24′24″ W.)
Excela Health Latrobe Hospital Heliport
(Lat. 40°19′13″ N., long. 79°23′37″ W.)

That airspace extending upward from 700 feet above the surface within a 12-mile radius of Arnold Palmer Regional Airport, and within a 6-mile radius of Excela Health Latrobe Hospital Heliport.

Issued in College Park, Georgia, on April 30, 2012.

Barry A. Knight,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2012–11407 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–107548–11]

RIN 1545–BK10

Modifications to Definition of United States Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this **Federal Register**, the IRS and the Treasury Department are issuing temporary regulations relating to the treatment of upfront payments made pursuant to certain notional principal contracts. The temporary regulations provide that certain obligations of United States persons arising from upfront payments made by controlled foreign corporations pursuant to contracts that are cleared by a derivatives clearing organization or clearing agency do not constitute United States property. The text of the temporary regulations also serves as the text of these proposed regulations.

DATES: Comments and requests for a public hearing must be received by August 9, 2012.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–107548–11), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–107548–11), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically, via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–107548–11).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Kristine A. Crabtree, (202) 622–3840; concerning submissions of comments or a request for a public hearing, Oluwafunmilayo Taylor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

The temporary regulations published in the Rules and Regulations section of this issue of the **Federal Register** establish an exception to the definition of United States property (within the meaning of section 956(c)) for obligations of United States persons arising from certain upfront payments made with respect to certain contracts that are properly classified as notional principal contracts for U.S. Federal income tax purposes and that are cleared by a derivatives clearing organization or clearing agency. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small entities.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under **ADDRESSES**. In addition to the specific requests for comments made elsewhere in this preamble or the preamble to the temporary regulations, the IRS and the Treasury Department request comments on all aspects of the proposed rules. All comments will be available at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person who timely submitted written comments. If a public hearing is scheduled, notice of the date, time, and place of the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Kristine A. Crabtree of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendment to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.956–2(b)(1)(xi) also issued under 26 U.S.C. 956(e). * * *

Par. 2. Section 1.956–2 is amended by adding new paragraphs (b)(1)(xi) and (f) to read as follows:

§ 1.956–2 Definition of United States property.

* * * * *

(b)(1)(xi) [The text of this proposed amendment is the same as the text of § 1.956–2T(b)(1)(xi) published elsewhere in this issue of the **Federal Register**].

* * * * *

(f) [The text of this proposed amendment is the same as the text of § 1.956–2T(f) published elsewhere in this issue of the **Federal Register**].

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2012–11327 Filed 5–10–12; 8:45 am]

BILLING CODE 4830–01–P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2200

Request for Public Comment on Settlement Part Program

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Request for comment.

SUMMARY: The Occupational Safety and Health Review Commission (Review Commission) invites the public to comment on the Review Commission's Settlement Part program.

DATES: Written comments must be submitted on or before June 25, 2012.

ADDRESSES: Submit all written comments, identified by the title ''Settlement Part Public Comment,'' by mail or hand delivery to John X. Cerveny, Deputy Executive Secretary, Occupational Safety and Health Review Commission, 1120 20th Street NW.,

Washington, DC 20036–3457, by fax to 202–606–5050, or by email to *fedreg@oshrc.gov.*

FOR FURTHER INFORMATION CONTACT: John X. Cerveny, Deputy Executive Secretary, Occupational Safety and Health Review Commission, 1120 20th Street NW., Ninth Floor, Washington, DC 20036–3457; Telephone (202) 606–5706; email address: *fedreg@oshrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Review Commission's Settlement Part program, codified at 29 CFR 2200.120, is designed to encourage settlements on contested citations issued by the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) and to reduce litigation costs. The Settlement Part program is a form of alternative dispute resolution (ADR) under which larger contested OSHA citations (those with an aggregate penalty amount of $100,000 or greater) docketed at the Review Commission are required to undergo a ''settlement procedure'' prior to the initiation of conventional hearing procedures before a Review Commission administrative law judge (ALJ). Under the mandatory Settlement Part, such a case is first assigned to a ''Settlement Judge'' who will issue a discovery order and supervise all discovery proceedings. Discovery may be limited or suspended entirely in advance of any conference before the settlement judge. After any discovery proceedings, the Settlement Judge conducts settlement proceedings which include conferences with the parties in order to identify or narrow factual and legal issues and/or to settle the case(s). All statements made and all information presented during the course of settlement proceedings are regarded as confidential and are not to be divulged outside of the settlement proceedings except with the consent of the parties. If Settlement Part proceedings do not result in a settlement, the case is assigned to a hearing judge (normally a judge other than the Settlement Judge) who will handle the matter under conventional hearing procedures.

The Review Commission's Mandatory Settlement Part was first instituted as a pilot program by the Review Commission in 1999 and was limited to contests of $200,000 or more. *See* 64 FR 8243 (Feb. 19, 1999). During the pilot period, the Settlement Part program was the subject of a study performed by the Indiana Conflict Resolution Institute at the School of Public and Environmental Affairs of Indiana University (IU). That study, which was completed in August 2000, attempted to examine several aspects of the pilot Settlement Part program in order to make recommendations concerning continuation of the program and any changes that might improve the Settlement Part process. In general, IU concluded that Settlement Part resulted in a high settlement rate and that both internal and external stakeholders were satisfied with program requirements and the Review Commission's role.

II. Current Status of Settlement Part Program Review

The Review Commission's Settlement Part program has changed in three important ways since it was initiated in 1999. First, it was made a permanent program in 2000. *See* 65 FR 58350 (Sept. 29, 2000). Second, it was expanded to encompass contests of $100,000 or more in 2005. *See* 70 FR 22785 (May 3, 2005). Last, the 2005 revisions also provided for discovery to take place prior to initiation of settlement conferences. However, the basic premise and foundation of Settlement Part has not been reviewed on an in-depth basis since completion of the IU study in 2000.

After the passage of twelve years and the substantial experience gained in Settlement Part use since that time, the Review Commission is considering what additional steps, if any, may be taken to improve, expand upon, or otherwise modify existing Settlement Part procedures. The Review Commission has again contracted with IU and data is being collected in order to examine the efficiency and effectiveness of its Settlement Part program in achieving its goals. IU will review case processing data obtained from the Review Commission's case tracking system and has interviewed Review Commission personnel. IU plans on distributing a survey to U.S. Department of Labor attorneys, employer counsel or representatives, counsel for employee representatives and employee representatives, and decision makers who personally participated in settlement cases from February 15, 2011 through February 14, 2012 that completed the settlement part process. IU plans an additional survey of a control group of participants with similar roles, in regular conventional proceedings between February 15, 2011 through June 30, 2012 where between $50,000 and $99,999 is at issue. Both surveys include questions that address the settlement process and do not include questions that ask about the substance or confidences of any particular case. These two surveys are voluntary and individual responses will be confidential. The Review Commission will obtain all appropriate clearances, including Office of Management and Budget survey collection approvals, before any surveys of participants involved in Review Commission settlement and conventional proceedings are distributed by IU.

III. Issues for Public Comment

In addition to the data collected from our case tracking systems and participant surveys, we invite comments on the efficiency and effectiveness of the Settlement Part program from the general public. Comments on specific aspects of the program are most helpful. Below are several questions that may be considered in commenting on the Settlement Part program.

1. How should the Review Commission define ''success'' for its Settlement Part program? Should issues of time and cost savings be principal considerations, or should other issues (e.g., transparency, avoidance of litigation, fairness to parties) infuse the process?

2. Has use of Settlement Part improved cooperation among the parties in encouraging settlements? For example, is there more cooperation among the parties regarding abatement? Does the Settlement Part promote future compliance?

3. What is the appropriate role of employees and/or their representatives in the Settlement Part process? How might the Review Commission's Settlement Part rules address these roles?

4. One concern that has been voiced by some is that the confidentiality provisions of Settlement Part are too broad and comprehensive, and while perhaps appropriate for private arbitration agreements, may be inappropriate in the current context. Conversely, a concern expressed by some with substantial ADR experience, is that it is not feasible to expect settlement of a matter if a substantial degree of confidentially is not maintained. Do existing Settlement Part rules adequately address the concerns of parties regarding confidentiality? How might the Review Commission's Settlement Part rules balance the competing interests of transparency and confidentiality, as well as creating an environment that will either foster or promote the resolution of contests?

5. Are the Review Commission's existing Settlement Part discovery rules appropriate for use in an ADR setting?

6. Should mandatory Settlement Part rules be amended to provide an option for the Chief ALJ to assign a case to

Settlement Part where the issues are particularly complex even if specific dollar thresholds are not met? Should the Chief ALJ be able to adjust the dollar thresholds for cases eligible for mandatory settlement part processes based upon the Review Commission's case load?

7. Should cases be permitted to remain in mandatory settlement part proceedings for more than 18 months without the approval of the Chief ALJ?

8. Should the parties be allowed to elect to not participate in a mandatory settlement part proceeding and, instead, request that the case proceed directly to a hearing on the merits?

The Review Commission welcomes any other comments or suggestions regarding Settlement Part.

Dated: May 1, 2012.

Debra Hall,

Acting Executive Director.

[FR Doc. 2012–11080 Filed 5–10–12; 8:45 am]

BILLING CODE 7600–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0345; FRL–9671–2]

State of Hawaii; Regional Haze Federal Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public hearing.

SUMMARY: EPA is announcing that public hearings will be held on May 31, 2012 and June 1, 2012 for the proposed rule, ''State of Hawaii; Regional Haze Federal Implementation Plan'', which will be posted on EPA's Web site by May 16, 2012.

DATES: The public hearings will be held on May 31, 2012 and June 1, 2012. See **SUPPLEMENTARY INFORMATION** section for further details about the public hearings.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for hearing locations.

FOR FURTHER INFORMATION CONTACT: If you have questions about the public hearings, please contact Gregory Nudd, EPA Region 9, 415–947–4107, *nudd.gregory@epa.gov.* If you are a person with a disability under the ADA and require a reasonable accommodation for this event, please contact Philip Kum at *kum.philip@epa.gov* or at (415) 947–3566 by May 16, 2012.

SUPPLEMENTARY INFORMATION: Section 169A of the Clean Air Act (CAA) establishes as a national goal the ''prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from manmade air pollution.'' Hawaii has two Class I areas: Hawaii Volcanoes National Park on the Big Island and Haleakala National Park on Maui.

Regional haze is visibility impairment caused by the cumulative air pollutant emissions from numerous sources over a wide geographic area. EPA's proposed Regional Haze Federal Implementation Plan (FIP) for Hawaii will address the requirements of the CAA and EPA's regulations regarding regional haze. The proposed rule, ''State of Hawaii; Regional Haze Federal Implementation Plan'', will be available by May 16, 2012 on the following Web site: *http://www.epa.gov/region9/air/actions/hawaii.html* and will subsequently be published in the **Federal Register**.

The proposed rule and information on which the proposed rule relies will also be available in the docket for this action. Generally, documents in the docket for this action will be available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

Public hearings: EPA will hold two public hearings at the following dates, times and locations to accept oral and written comments into the record:

Date: May 31, 2012.
Time: Open House: 5:30–6:30 p.m.
Public Hearing: 6:30–8:30 p.m.
Location: The University of Hawaii, Maui College in the Pilina Multipurpose Room, 310 W. Kaahumanu Ave., Kahului, Hawaii 96732.

Date: June 1, 2012.
Time: Open House: 4:30–5:30 p.m.
Public Hearing: 5:30–7:30 p.m.
Location: Waiakea High School in the Cafeteria, 155 W. Kawili St., Hilo, Hawaii 96720.

To provide opportunities for questions and discussion, EPA will hold open houses prior to the public hearings. During these open houses, EPA staff will be available to informally answer questions on our proposed action and this supplemental proposed rule. Any comments made to EPA staff during the open houses must still be provided formally in writing or orally during a public hearing in order to be considered in the record.

The public hearings will provide the public with an opportunity to present data, views, or arguments concerning the proposed Regional Haze FIP for Hawaii. EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. Please consult the proposed rule for guidance on how to submit written comments to EPA.

At the public hearing, the hearing officer may limit the time available for each commenter to address the proposal to five minutes or less if the hearing officer determines it is appropriate. Any person may provide written or oral comments and data pertaining to our proposal at the public hearing. We will include verbatim transcripts, in English, of the hearing and written statements in the rulemaking docket.

Dated: May 1, 2012.

Elizabeth Adams,

Acting Air Division Director, Region IX.

[FR Doc. 2012–11426 Filed 5–10–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 441, and 447

[CMS–2370–P]

RIN 0938–AQ63

Medicaid Program; Payments for Services Furnished by Certain Primary Care Physicians and Charges for Vaccine Administration Under the Vaccines for Children Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement new requirements in sections 1902(a)(13), 1902(jj), 1932(f), and 1905(dd) of the Social Security Act, as amended by the Patient Protection and Affordable Care Act of 2010 (the

Affordable Care Act). It implements Medicaid payment for primary care services furnished by certain physicians in calendar years (CYs) 2013 and 2014 at rates not less than the Medicare rates in effect in those CYs or, if greater, the payment rates that would be applicable in those CYs using the CY 2009 Medicare physician fee schedule conversion factor (CF). This minimum payment level applies to specified primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine, and also applies to services paid through Medicaid managed care plans. It would also provide for a 100 percent Federal matching rate for any increase in payment above the amounts that would be due for these services under the provisions of the State plan as of July 1, 2009. In this proposed rule, we specify which services and types of physicians qualify for the minimum payment level in CYs 2013 and 2014, and the method for calculating the payment amount and any increase for which increased Federal funding is due.

In addition, this proposed rule would update the interim regional maximum fees that providers may charge for the administration of pediatric vaccines to federally vaccine-eligible children under the Pediatric Immunization Distribution Program, more commonly known as the Vaccines for Children (VFC) program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 11, 2012.

ADDRESSES: In commenting, please refer to file code CMS–2370–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.*

Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2370–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2370–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Mary Cieslicki, (410) 786–4576, or Linda Tavener, (410) 786–3838, for issues related to payments for primary care physicians.

Mary Beth Hance, 410–786–4299, for issues related to charges for the administration of pediatric vaccines.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This proposed rule implements new requirements in sections 1902(a)(13), 1902(jj), 1905(dd) and 1932(f) of the Social Security Act requiring payment by State Medicaid agencies of at least the Medicare rates in effect in CYs 2013 and 2014 or, if higher, the rate using the CY 2009 conversion factor (CF) for primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine. Also, this proposed rule implements the statutory payment provisions uniformly across all States, defines, for purposes of enhanced Federal match, eligible primary care physicians, identifies eligible primary care services, and specifies how the increased payment should be calculated. Finally, this proposed rule provides general guidelines for implementing the increased payment for primary care services delivered by managed care plans.

This proposed rule also proposes updates to vaccine rates that have not been updated since the VFC program was established in 1994. We propose to update these rates due to inflation and we are proposing to use the Medicare Economic Index (MEI).

2. Summary of the Major Provisions

a. Payments to Physicians for Primary Care Services

This proposed rule would implement Medicaid payment for primary care services furnished by certain physicians in calendar years (CYs) 2013 and 2014 at rates not less than the Medicare rates in effect in those CYs or, if greater, the payment rates that would be applicable in those CYs using the CY 2009

conversion factor (CF). It would also provide for a 100 percent Federal matching rate for any increase in payment above the amounts that would be due for these services under the provisions of the State plan as of July 1, 2009. This proposed rule is necessary to promote access to primary care services in the Medicaid program before and during the expansion of coverage that begins in 2014. These proposals implement the Affordable Care Act.

b. Vaccine Administration Under the Vaccines for Children (VFC) Program

This proposed rule proposes to update the interim regional maximum fees that providers may charge for the administration of pediatric vaccines to federally vaccine-eligible children under the Pediatric Immunization Distribution Program, more commonly known as the Vaccines for Children (VFC) program. We are proposing to use the MEI which is a price index that is used by CMS to update Medicare physician payments. We believe the MEI is the best tool to update these rates because: (1) It reflects input price inflation faced by physicians inclusive of the time period when the national average was established in 1994, and (2) we believe that input prices associated with this specific type of physician-provided service are consistent with overall input prices. The MEI was most recently updated at the end of 2011.

3. Summary of the Costs and Benefits

Provision description	Total costs	Total benefits
Payments to Physicians for Primary Care Services.	The overall economic impact of this proposed rule is an estimated $5.52 billion in CY 2013 and $5.66 billion in CY 2014. In CY 2013, the Federal cost is approximately $5.74 billion with $225 million in State savings. In CY 2014, the Federal cost is approximately $5.96 billion with $300 million in State savings. Of this amount, the aggregate economic impact, as a result of this proposed rule requiring States to reimburse specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum during CYs 2013 and 2014, is estimated at an additional $970 million in Federal costs. The Federal costs for funding that increase, in State payments during CYs 2013 and 2014, are estimated at $490 million and $480 million, respectively.	The overall benefit of this rule is the expected increase in provider participation by primary care physicians resulting in better access to primary and preventive health services by Medicaid beneficiaries.
Increase in Vaccine for Children Program Maximum Ceiling.	This rule raises the maximum rate that States could pay providers for the administration of vaccines under the VFC program in subsequent years after CY 2014. States are not anticipated to raise their VFC ceilings in 2013 and 2014 because of the implementation of the primary care payment increase.	The overall benefit of this provision is that it gives States the ability to increase their VFC vaccine administration rates.

C. Background

1. Payments to Physicians for Primary Care Services: Statutory and Regulatory Framework

a. Improving Primary Care

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) was enacted; together they are known as the Affordable Care Act. This proposed rule would implement the new requirements in sections 1902(a)(13), 1902(jj), 1932(f), and 1905(dd) of the Act, as amended by the Affordable Care Act. Section 1902(a)(13) of the Act requires payment by State Medicaid agencies of at least the Medicare rates in effect in calendar years (CYs) 2013 and 2014 or, if higher, the rate that would be applicable using the CY 2009 Medicare conversion factor (CF), for primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine.

Primary care for any population is critical to ensuring continuity of care, as well as to providing necessary preventive care, which improves overall health and can reduce health care costs. The availability of primary care is particularly important for Medicaid enrollees to establish a regular source of care and to provide care to a population that is more prone to chronic health conditions that can be appropriately managed by primary care physicians. Primary care physicians provide services that are considered to be a core part of the Medicaid benefit package. Additionally, these physicians can perform the vital function of coordinating care, including specialty care.

As we move towards CY 2014 and the expansion of Medicaid eligibility, it is critical that a sufficient number of primary care physicians participate in the program. Section 1902(a)(13) of the Act will encourage primary care physicians to participate in Medicaid by increasing payment rates.

b. Medicaid Payment to Providers

Section 1902(a)(30)(A) of the Act requires that Medicaid payments be consistent with efficiency, economy, and quality of care and be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. In meeting these requirements, States have broad discretion in establishing and updating Medicaid service payment rates to primary care providers. For instance, many States reimburse based on the cost of providing the service, a review of the amount paid by commercial payers in the private market, or as a percentage of rates paid under the Medicare program for equivalent services. States may update

rates based on specific trending factors such as the MEI or a Medicaid specific trend factor that incorporates a State-determined inflation adjustment rate. Increasingly, States are providing medical assistance through managed care plans under contracts with managed care organizations (MCOs) and other organized delivery systems, such as prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). The contract between the State and the managed care plan requires the plan to provide access to and make payments to primary care physicians using the funds the State pays to the managed care plan. Indeed, according to the Medicaid and CHIP Payment and Access Commission (MACPAC), 49 million Medicaid beneficiaries receive care through some form of Medicaid managed care.

Section 1902(a)(13)(C) of the Act requires that States pay a minimum payment amount for certain primary care services delivered by designated primary care physicians. Primary care services are defined in new section 1902(jj) of the Act and include certain specified procedure codes for evaluation and management (E&M) services and certain vaccine administration codes. Under this provision, States must reimburse at least as much as the Medicare physician fee schedule (MPFS) rate in CYs 2013 and 2014 or, if greater, the payment rate that would apply using the CY 2009 Medicare CF. The requirement for payment at the Medicare rate extends to primary care services paid on a fee-for-service (FFS) basis, as well as to those paid by Medicaid managed care plans. This proposed regulation would specify which services and physicians qualify for the increased payment amount in CYs 2013 and 2014, and the method for calculating that payment.

Section 1905(dd) of the Act provides for a higher FMAP for the required increase in physician payment. For FFS expenditures, the FMAP rate will be 100 percent of the difference between the Medicaid State plan rate in effect on July 1, 2009, and the amount required to be paid under section 1902(a)(13)(C) of the Act. That means that States will be fully reimbursed for these increased payments by the Federal government.

One goal of this proposed rule is to define the payment provisions further so that States may uniformly identify the rate differential. Specifically, we propose a payment methodology that would take into account potential changes in Medicare rates between CYs 2013 and 2014 and CY 2009 that is independent of the legislatively required payment reductions caused by Medicare's sustainable growth rate mechanism. Furthermore, this proposed rule would address Medicare's use of different fee schedules that take into account the site of service (for example, physician's office, or outpatient department of a hospital) and geographical location of the provider.

The Affordable Care Act amended section 1932(f) of the Act to clarify that States must incorporate the requirement for increased payment to primary care providers into contracts with managed care organizations. We propose general guidelines for States to follow when identifying the amounts by which MCOs must increase existing payments to primary care providers, and any additional capitation costs to the State attributable to such required increases in existing payments. We are also proposing to extend this same treatment to PIHPs and PAHPs through regulations at part 438, to the extent that primary care provider payments are made by these entities.

We seek comments on how best to implement through regulation the requirement that managed care plans (whether capitated, partially capitated or on a FFS basis) pay primary care providers at the Medicare rate for primary care services, consistent with those paid on a FFS basis. Additionally, we seek comments from States and others on the best way to adequately identify the increase in managed care capitation payments made by the State that is attributable to the increased provider payment, for the purpose of claiming 100 percent FFP. We are particularly interested in ensuring that primary care physicians receive the benefit of the increased payment. Section 1932(f) of the Act, as amended by the Affordable Care Act, requires that the managed care contracts pay providers at the applicable Medicare rate levels. We propose to review managed care contracts to ensure that this requirement is imposed on managed care plans by the State. We also propose to require managed care plans to report to the State the payments made to physicians under this provision to justify any adjustments to the capitation rates paid by the State under the contract. In proposing this approach, we are mindful of balancing the need for adequate documentation of the payment with the administrative burden it places on States and managed care plans. We are requesting comment on these provisions and additional suggestions on how to ensure that managed care plans provide the necessary data to the State, as well as how to ensure and monitor that managed care plans appropriately pass on to physicians the portion of the increased capitation rate that is attributable to the primary care rate increase.

This proposed rule also addresses identification of the rate differential eligible for 100 percent Federal matching funds for vaccine administration, as set forth in section 1905(dd) of the Act. In 2011, the vaccine administration billing codes were changed so it is not possible to track the Medicaid State plan rate in CY 2009 directly to the rates applicable in CYs 2013 and 2014. We are requesting comment on our proposal for imputing the CY 2009 rate.

c. Medicare Payment to Primary Care Providers

Medicare provides health insurance coverage to people who are aged 65 and over, or who meet other special criteria, under title XVIII of the Act. For institutional care, such as hospital and nursing home care, Medicare makes payments to providers using prospective payment systems. Payment for physicians' services under Medicare is based on the MPFS. The MPFS assigns relative value units (RVUs) for each procedure, as well as practice cost indices (GPCIs) for geographic variations in payments, and a global CF, which converts RVUs into dollars. Individual fee schedule amounts for the MPFS are the product of the geographic adjustment, RVUs, and CF. Site of service (for example, physician office or outpatient hospital) is reflected as an adjustment to the RVUs. We generally issue the MPFS final rule for the subsequent calendar year on or before November 1st each year. The MPFS final rule includes the RVUs and CF for the upcoming calendar year, which permits the calculation of rates. Updates may occur throughout the year, but normally occur quarterly.

2. Vaccine Administration Under the Vaccines for Children (VFC) Program

The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993), (Pub. L. 103–66), created the Vaccines for Children (VFC) Program), which became effective October 1, 1994. Section 13631 of OBRA 1993 added section 1902(a)(62) to the Act to require that States provide for a program for the purchase and distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children in accordance with section 1928 of the Act. Section 1928 of the Act requires each State to establish a VFC Program (which may be administered by the State Department of Health) under which certain specified groups of children are entitled to receive qualified

pediatric immunizations without charge for the cost of the vaccine.

Under the VFC Program, a provider, in administering a qualified pediatric vaccine to a federally vaccine-eligible child, may not impose a charge for the cost of the vaccine. Section 1928(c)(2)(C)(ii) of the Act allows a provider to impose a fee for the administration of a qualified pediatric vaccine as long as the fee, in the case of a federally vaccine-eligible child, does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration). However, a provider may not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents or legal guardian to pay the administration fee.

II. Provisions of the Proposed Regulation

A. Payments to Physicians for Primary Care Services

1. Primary Care Services Furnished by Physicians With Specified Specialty and Subspecialty (§ 447.400)

a. Specified Specialties and Subspecialties

Section 1902(a)(13)(C) of the Act specifies that physicians with a specialty designation of family medicine, general internal medicine, and pediatric medicine qualify as primary care providers for purposes of increased payment. This proposed rule provides that services provided by subspecialists related to the primary care specialists designated in the statute would also qualify for higher payment. These subspecialists would be recognized in accordance with the American Board of Medical Specialties designations. For example, a pediatric cardiologist would qualify for payment if he or she rendered one of the specified primary care services by virtue of that physician's subspecialty within the qualifying specialty of internal medicine. Additionally, this proposed rule would specify a method for States to use in identifying practitioners who may receive the increased payment.

The inclusion of subspecialists is based on three factors. We first considered that many primary care subspecialists render the primary care services specified in this rule. Stakeholders, including physicians, States, and independent policy makers strongly emphasized this point in their engagement with CMS on this proposed rule. Many stressed the importance of subspecialists, particularly pediatric subspecialists, in the provision of primary care and strongly recommended that they be eligible for the higher payment. Additionally, we see no justification for including only subspecialists in one specialty designation and, therefore, we are proposing that all subspecialists within the three specialty designations be eligible for increased payment for primary care services. Finally, we believe the statute provides the latitude to include related subspecialists within these specialty designations.

Therefore, we are proposing that all subspecialists recognized by the American Board of Medical Specialties within the three specialty designations be eligible for increased payment for primary care services. That is, we propose that all subspecialists within the specialty designations of family medicine, general internal medicine, and pediatric medicine as recognized by the American Board of Medical Specialties be eligible for increased payment. In this rule, we propose to specify how States would identify the specialists and subspecialists eligible for increased payment. Identification of eligible physicians is critical to ensure that only specified physicians receive increased payment.

Under our proposal, States would be required to establish a system to require physicians to identify to the Medicaid agency their specialty or subspecialty before an increased payment is made. For program integrity purposes, the State will be required to confirm the self-attestation of the physician before paying claims from that provider at the higher Medicare rate. We propose that this be done either by verifying that the physician is Board certified in an eligible specialty or subspecialty or through a review of physician's practice characteristics.

Specifically, for a physician who attests that he or she is an eligible primary care specialist or subspecialist but who is not Board certified (including those who are Board-eligible, but not certified), a review of the physician's billing history must be performed by the Medicaid agency. We are proposing that at least 60 percent of the codes billed by the physician for all of CY 2012 must be for the E&M codes and vaccine administration codes specified in this regulation. For a new physician who enrolls during either CY 2013 or CY 2014 and who attests that he or she is within one of the eligible specialties or subspecialties and who is not Board certified, we propose that following the end of the CY in which enrollment occurs, the State would review the physician's billing history to confirm that 60 percent of codes billed during the CY of enrollment were for primary care services eligible for payment under sections 1902(a)(13)(C) and 1902(jj) of the Act.

To summarize, we would not limit specified providers to physicians who are Board certified. States would be required to verify the eligibility of non-Board certified physicians through a review of the physician's practice characteristics.

We developed this proposal for the use of a supporting history of codes billed to qualify physicians for increased payment after reviewing the statutory requirements for the Medicare Incentive Payments for Primary Care Services payments authorized by section 5501(a) of the Affordable Care Act, which amended section 1833 of the Act. That provision specifically requires that primary care services account for at least 60 percent of the allowed charges billed by a practitioner for services to be eligible for increased payment. We propose that the same standard be applied to the Medicaid payments under section 1902(a)(13)(C) of the Act although we propose that verification would be based on the number of codes billed for the specified primary care services, rather than charges. The use of billing codes rather than allowed charges helps to assure that physicians providing a certain volume of primary care services are uniformly recognized for higher payment across States, regardless of variations in service charges.

We are seeking comment on whether 60 percent or some other percentage threshold would be more appropriate to determine whether a non Board certified physician qualifies for increased payment.

In developing the overall requirements for verification of physician self-attestation, we considered that there are no pre-existing Federal Medicaid requirements concerning provider designation of a specialty or subspecialty. Because State practices vary on recognizing specialty or subspecialty designations for different purposes, reliance solely on self-attestation would result in a lack of uniformity in the application of minimum payment levels. Self-attestation alone would not provide an objective and auditable standard to document that a provider is one of the types of primary care physicians designated in statute. For this reason, we believe imposing the requirement for either Board certification in a nationally-recognized specialty or subspecialty or a supporting history of codes billed using the Medicare standard is merited.

When making a payment, the State would have the choice of initially reimbursing a newly enrolled physician at the Medicare rate or the Medicaid State plan rate used for services provided by physicians who do not qualify for the increased payment. If the State chooses to reimburse a physician initially at the higher Medicare rate and later finds through the review of codes billed that the physician did not qualify, increased payments to which the provider was not entitled under the State plan would be considered as overpayments. Conversely, the State could choose to reimburse the newly enrolled physician at the Medicaid State plan rate applicable to services provided by physicians who do not qualify for increased payment, and then make supplemental payments promptly upon determining qualification for the increased payments.

We are soliciting comments on whether the proposed timeframes, or something else, for establishing a supporting history of codes billed for a physician who is not Board certified is appropriate. We are attempting to minimize any implementation burden while also ensuring that proper audit controls are in place to prevent inappropriate application of this provision.

b. Furnished by a Specified Physician

Section 1902(a)(13)(c)of the Act requires increased payment for ''primary care services furnished in CYs 2013 and 2014 by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine.'' This regulation would specify that the increased payment applies only for services under the ''physicians' services'' benefit at section 1905(a)(5)(A) of the Act and in regulations at § 440.50.

Increased payment would not be available for services provided by a physician delivering services under any other benefit under section 1905(a) of the Act such as, but not limited to, the FQHC or RHC benefits because, in those instances, payment is made on a facility basis and is not specific to the physician's services. Section 1902(a)(13)(c) of the Act requires payment ''for primary care services* * * furnished by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine at a rate no less than 100 percent of the payment rate that applies to such services and physicians under Part B of Title XVIII.'' Therefore, we believe that the statute limits payment to physicians who, if Medicare providers, would be reimbursed using the MPFS. The MPFS is not used to reimburse physicians in settings such as FQHCs or RHCs; therefore, we believe physicians delivering primary care services at FQHCs and RHCs are not eligible for increased payments under section 1902(a)(13) of the Act. Furthermore, we note that the Medicaid statute already provides a payment methodology for FQHCs and RHCs that is designed to reimburse those providers at cost.

In specifying that payment is made for qualified primary care services under the physicians' services benefit at § 440.50, the increased payment for primary care services would be required for services furnished ''by or under the personal supervision'' of a physician who is one of the primary care specialty or subspecialty types designated in the regulation. In Medicaid, many primary care physician services are actually furnished under the personal supervision of a physician by nonphysician practitioners, such as nurse practitioners and physician assistants. Such services are billed under the supervising physician's program enrollment number and are treated in both Medicare and Medicaid as services of the supervising physician. Consistent with that treatment, we propose that primary care services would be paid at the higher rates if properly billed under the provider number of a physician who is enrolled as one of the specified primary care specialists or subspecialists, regardless of whether furnished by the physician directly, or under the physician's personal supervision. This would align with Medicaid's longstanding practice in providing physician services, as well as Medicare's Part B FFS payment methodology for professional services. Additionally, this policy would recognize the important role that nonphysician practitioners working under the supervision of physicians have in the delivery of primary care services.

c. Eligible Primary Care Services (§ 447.400(b))

We propose that Healthcare Common Procedure Coding System (HCPCS) E&M codes 99201 through 99499 and vaccine administration codes 90460, 90461, 90471, 90472, 90473 and 90474 or their successors would be eligible for higher payment and FFP. These codes are specified by the statute and include those primary care E&M codes not reimbursed by Medicare.

We believe that non-Medicare covered primary care services should be included because these services represent a core component of services commonly delivered in the Medicaid program. We reviewed Medicaid payment data from 2007, 2008, and 2009 for these services as a percentage of primary care expenditures, and found that they represent 6 percent of primary care payments (as distinguished from service volume). We believe this percentage warrants the inclusion of these non-Medicare reimbursed codes to achieve the purpose of encouraging primary care providers to serve the Medicaid population.

Where there are differences in codes reimbursed by Medicaid and Medicare we attribute this mostly to the fact that children represent a population not typically served by the Medicare program. As a result, the scope of primary care services is not equivalent between the two programs. We believe that the statute provides the latitude to include codes for which the Medicare program sets and publishes RVUs, even if Medicare payment is not actually made for the service.

Specifically, we are proposing to include as primary care services the following E&M codes that are not reimbursed by Medicare:

- New Patient/Initial Comprehensive Preventive Medicine—codes 99381 through 99387;
- Established Patient/Periodic Comprehensive Preventive Medicine—codes 99391 through 99397;
- Counseling Risk Factor Reduction and Behavior Change Intervention—codes 99401 through 99404, 99408, 99409, 99411, 99412, 99420 and 99429;
- E&M/Non Face-to-Face physician Service—codes 99441 through 99444.

2. Amount of Required Minimum Payments (§ 447.405)

Section 1902(a)(13)(C) of the Act requires payment not less than the amount that applies under the MPFS in CYs 2013 and 2014 or, if greater, the payment rate that would be applicable if the 2009 CF were used to calculate the MPFS.

a. Use of Fee Schedule Amount Applicable to the Geographic Location of Service

We are proposing that States be required to use the MPFS rate applicable to the site of service and geographic location of the service at issue. The Medicare Part B rates vary by geographic location and site of service. For example, rates are higher for services provided in an office setting as opposed to the outpatient hospital setting. We propose that States would be required to use the MPFS payment amounts applicable to the site of service and geographic location because we

believe these are integral to the MPFS payment system. Individual fee schedule amounts for the MPFS are the product of the geographic adjustment, RVUs, and CF that converts adjusted RVUs into dollar amounts. Site of service is reflected as an adjustment to the RVUs used to set the rate.

We are proposing that States be required to use the MPFS as published by CMS. Medicare primary care incentive payments made pursuant to section 5501 of the Affordable Care Act, which amended section 1833 of the Act, would not be included. Section 5501(a) provides for incentive payments for a subset of the codes covered by this regulation. The payments are not made as increases in fee schedule amounts and are not reflected in the MPFS.

b. Payment for Services Unique to Medicaid

For services reimbursed by Medicaid but not Medicare, we propose that payment would be made under a fee schedule developed by CMS and issued prior to the beginning of CYs 2013 and 2014. We propose that rates for non-Medicare reimbursed services would be established using the Medicare CF in effect in CYs 2013 and 2014 (or the CY 2009 CF, if higher) and the RVUs recommended by the American Medical Association's (AMA) Specialty Society Relative Value Update Committee (RUC) and published by CMS for CYs 2013 and 2014. We are specifically seeking comments from States and others on the most appropriate way to set payment rates for services not reimbursed by Medicare.

c. Updates to Medicare Part B Fee Schedule

We recognize the potential for multiple updates to the MPFS in CYs 2013 and 2014. Those rates are published by CMS on or before November 1st of the preceding calendar year, but are subject to periodic adjustments or updates throughout the calendar year. In addition, the Medicare Part B rates vary by geographic location and site of service.

We propose to permit States the option of complying with the requirements of section 1902(a)(13)(C) of the Act by either adopting annual rates or by using a methodology to update rates to reflect changes made by Medicare during the year. That is, States could adopt the MPFS in effect at the beginning of CYs 2013 and 2014 (or, if the CY 2009 CF is higher, the CY 2013 or CY 2014 RVUs multiplied by the CY 2009 MPFS CF), and apply those rates throughout the applicable calendar year without adjustments or updates. Using this methodology, mid-year updates made to the MPFS during the respective calendar year would not be reflected in Medicaid payments. Alternatively, a State could elect to adjust Medicaid payments to reflect mid-year updates made to the MPFS, but the State's methodology would have to specify the timing for such adjustments.

In consulting with State Medicaid agencies and other stakeholders, we were urged not to require multiple rate adjustments based on fluctuations in the MPFS, but to identify the MPFS for each year as of a single point in time. That annual fee schedule would serve as the basis of the rates paid by Medicaid during each of the 2 years that section 1902(a)(13)(C) of the Act is in effect. Based on the feedback, we propose giving States the choice to apply or not apply mid-year updates.

3. State Plan Requirements (§ 447.410)

Under the proposed rule, States would be required to submit a State plan amendment (SPA) to reflect the fee schedule rate increases for eligible primary care physicians under section 1902(a)(13)(A) of the Act. The purpose of this proposed requirement is to assure that when States make the increased reimbursement to physicians, they have State plan authority to do so and they have notified physicians of the change in reimbursement as required by Federal regulations.

4. Availability of Federal Financial Participation (FFP) (§ 447.415)

Section 1905(dd) of the Act allows States to receive 100 percent FFP for expenditures equal to the difference between the Medicaid State plan rate for primary care services in effect on July 1, 2009, and the Medicare rates in effect in CYs 2013 and 2014 or, if greater, the payment rate that would be applicable using the CY 2009 Medicare CF. To claim the enhanced Federal match, States must make payments to specified physicians at the appropriate MPFS rate and must develop a method of identifying both the rate differential and eligible physicians for services reimbursed on an FFS for service basis and through managed care plans. States must be able to document the difference between the July 1, 2009 Medicaid rate and the applicable Medicare rate for specified providers that is claimable at the 100 percent matching rate. This requirement applies also to services provided to individuals eligible for both Medicaid and Medicare. This means that increased FFP will be available also for higher Medicaid payments for Medicare cost sharing for individuals who are eligible for both programs.

a. FFP in Payments for Individuals Eligible for Both Medicare and Medicaid

When a service is provided to an individual who is eligible for Medicare and Medicaid, Medicare reimburses the physician 80 percent of its fee schedule rate while Medicaid pays the remaining cost. Currently, States have two options for such payments consistent with section 1902(n) of the Act. A State may pay the provider the full amount necessary to result in aggregate payment to the provider equal to the MPFS rate (the full Medicare cost sharing amount), or only the amount (if any) to result in aggregate payment equal to the State's Medicaid rate. For example, under the second option, if the Medicare allowed amount is $100 and the Medicaid rate is $75, then Medicare pays $80 and there is no additional amount paid by Medicaid. Historically, most States have chosen to pay providers only up to the lower Medicaid rate.

In CYs 2013 and 2014, the Medicaid rate for primary care services by the specified physicians will equal the Medicare rate. As a result, these physicians should receive payment up to the full Medicare rate for primary care services and 100 percent FFP will be available for the full amount of the Medicare cost sharing amount that exceeds the amount that would have been payable under the State plan in effect on July 1, 2009.

b. Identifying the July 1, 2009 Payment Rate

For the purpose of identifying the differential between the Medicaid rate and the Medicare rate, we propose to define the Medicaid ''rate'' under the approved Medicaid State plan as the final rate paid to a provider inclusive of all supplemental or increased payments paid to that provider. For example, many States currently pay physicians affiliated with academic medical centers the Medicaid State plan rate plus a supplemental amount that together equal the average amount paid by commercial third party payers. Therefore, in calculating the rate differential, these States would determine the CY 2009 rate inclusive of any supplemental payment.

c. Federal Funding for Increased Payments for Vaccine Administration

There are a number of factors affecting the identification of the cost of vaccine administration eligible for 100 percent FFP. They include the following issues:

- The structure of the billing codes for vaccine administration changed in 2011 such that four of the codes used in 2009 were replaced by two codes.

• Some States did not use the designated billing codes in effect in 2009.

• Prior to CY 2011, billing codes for vaccine administration did not permit payment for additional vaccine/toxoid components.

• Vaccines for Children (VFC) program requirements do not permit payment for each vaccine/toxoid component administered and limit provider charges to the regional VFC ceiling amount.

Prior to CY 2011 vaccine administration billing codes did not permit additional vaccine administration payments for vaccines with more than one vaccine/toxoid component. All providers, including those participating in the VFC program, received one payment per vaccine regardless of the number of vaccine/toxoid components. In this rule, we clarify that qualifying physicians, excluding those participating in the VFC program, must receive additional payments during CYs 2013 and 2014 for vaccines with multiple vaccine/toxoid components administered to Medicaid beneficiaries.

The vaccine administration billing codes recognized for reimbursement under the statute are: 90465, 90466, 90567, 90568, 90471, 90472, 90473 and 90474 or their successor codes. In 2011, the coding structure for vaccine administration changed such that four pediatric billing codes specified in section 1902(jj) of the Act (90465, 90466, 90767, and 90468) were replaced by just two billing codes (90460 and 90461). Moreover, the four deleted codes represented vaccine administrations by various routes (for example, intranasal vs. injectable) to children under age 8. However, new code 90460 represents the initial vaccine/toxoid administered through all routes to children under 18 while code 90461 represents additional vaccines/toxoids administered. As a result, States will not be able to identify the rate differential by comparing payments for the codes used in CY 2009 to those in use in CYs 2013 and 2014.

IMMUNIZATION CODES BEFORE AND AFTER 2011

Prior to 2011	Effective 2011
90465, 90466, 90467, 90468	90460, 90461
90471	90471
90472	90472
90473	90473
90474	90474

We propose that the State impute the CY 2009 rate for code 90460 based on the average payment amount for the deleted codes weighted by service volume. That is, each of the four CY 2009 rates for vaccine administration would be multiplied by their respective percentages of service volume and then added to determine one payment amount as demonstrated in the following example:

• 90465 = $10 × 0.50 service volume = $5.00

• 90466 = $10 × 0.10 service volume = $1.00

• 90467 = $8 × 0.30 service volume = $2.40

• 90468 = $8 × 0.10 service volume = 0.80

• Total cost equals $9.20 for the new, single code, 90460.

Code 90461 represents payment for the administration of additional vaccine/toxoid components in a vaccine. Code 90461 is an add-on code that cannot be used without code 90460. Because there were only single payments for vaccines prior to 2011, we believe the rate for code 90461 should be $0. We believe that this is an equitable method of setting the 2009 Medicaid base for code 90460, but welcome comments. For VFC providers, if the rate paid in July 2009 was lower than the regular Medicaid State plan administration fee for non-VFC providers, then the rate for VFC providers should be used as the 2009 base for code 90460. The majority of vaccines administered to Medicaid-eligible children under the age of 18 are administered as part of the Vaccines for Children (VFC) program. Section 1928(c)(2)(ii) of the Act provides that administration fees for vaccines provided under the VFC program cannot exceed the cost of administration as determined by the Secretary for that program. An additional concern for VFC vaccines is that, under the terms of the VFC program, providers can still only bill a flat fee per vaccine given by injection or by intranasal or oral routes, regardless of the number of vaccines/toxoid components, and must use only code 90460. In order to permit providers participating in the VFC program to benefit from the provisions of the Affordable Care Act, this rule proposes that States be required to reimburse VFC providers at the lesser of the 2013 and 2014 Medicare rates or the maximum regional VFC amount in those years. States should qualify for 100% FFP for these increased reimbursements. This policy is consistent with Medicare which limits provider payment to the lesser of the fee schedule amount or provider charges, since VFC provider charges are limited to the regional maximum administration fee. Since the VFC statute prohibits payment for additional vaccines/toxoids, VFC providers would only receive payment for administration fees billed using code 90460. We invite comment on whether these proposed provisions give sufficient effect to the legislative intent to increase provider payments to Medicare levels, or whether we should instead adopt policies that we describe below as alternatives considered in developing this proposed rule.

In proposing a method to determine the CY 2009 rate for code 90460, our goal is to identify a uniform methodology that is not administratively burdensome. We are seeking comments on this proposal and encourage States and other stakeholders to provide additional options for identifying the rate differential.

An additional issue related to the changes made by the Affordable Care Act for vaccine administration is that, in CY 2009, some States did not reimburse providers using the designated vaccine administration billing codes. Rather, some States paid providers on the basis of non standard billing codes developed for the purpose of identifying the type of vaccine being administered. In instances where both the vaccine and administration fee were billed using the vaccine code, States will be required to identify the CY 2009 payment for vaccine administration separate from the vaccine itself.

5. Primary Care Service Payments Made by Managed Care Plans, and Enhanced Federal Match (§ 438.6 and § 438.804)

As amended by the Affordable Care Act, section 1932(f) of the Act requires that the managed care plans pay physicians at the applicable Medicare rates. We propose to implement the managed care requirements through a State-by-State review of managed care contracts and applicable procedures. We will review managed care contracts to ensure that they—

• Provide for payment at the minimum Medicare primary care payment levels;

• Require that eligible physicians receive direct benefit of the payment increase for each of the primary care services specified in this rule. This requirement must be met regardless of whether a physician is salaried, or receives a fee for service or capitated payment. We emphasize that increased payment must correspond directly to the volume and payment amounts associated with the primary care services specified in this rule;

• Require that all information needed to adequately document expenditures eligible for 100 percent FFP is reported

by MCOs, PIHPs, and PAHPs to the States which, in turn, will report these data to CMS; and

• Specify that States must receive from MCOs, PIHPs and PHAPs data on primary care services which qualify for payment under this rule. The managed care reporting requirements would ensure that States have data on increased provider payments necessary to justify any adjustments to the capitation rates paid by the State under the contract.

Additionally, we will review each State's proposed methodology for identifying the discrete amount paid for each of the eligible primary care services that qualifies for 100 percent FFP. Both the managed care contracts and the State's methodology for identifying payment amounts made for each primary care services must be submitted to CMS for review prior to the start of CY 2013.

We acknowledge the diversity of payment arrangements between managed care plans and primary care physicians, and we will not require that managed care plans modify the terms of their payments to eligible primary care physicians beyond the increase in payments for primary care services required by the statute.

In proposing this approach, we are mindful of balancing the need for adequate documentation of the payment with the administrative burden it places on States and managed care plans. We are requesting comment on these provisions and additional suggestions on how to ensure that managed care plans provide the necessary data to the State, as well as how to ensure and monitor that managed care plans appropriately pass on to physicians the portion of the increased capitation rate that is attributable to the primary care rate increase.

States have expressed concern about their ability to align capitated payment made as of July 1, 2009 to payment made for services provided in CYs 2013 and 2014 for the purpose of claiming increased FFP. We recognize the particular challenges inherent in identifying the payment differential eligible for 100 percent FFP for primary care services provided by managed care plans because such payments are not necessarily linked to individual services and physicians. We believe that the most reasonable way to apply this provision for managed care rates is to do the following:

Step I: Identify the proportion of total capitation linked to primary care.

Step II: Identify the fee schedule amount incorporated into the actuarial model for primary care services represented by the proportion of payment for primary care services. Here, we assume the visit rate equals $25.

Step III: Determine the annualized cost built into the actuarial model for primary care. Here we assume 8 visits annually. $25 per visit rate × 8 visits annually = $200

Step IV: Determine the per visit cost discounted for volume. $200/12 = $16.67

In this example, $16.67 equals the imputed amount of the payment made on a fee for services basis for an individual primary care service. The State would compare this amount to the Medicare rate paid in CYs 2013 and 2014 to determine the payment differential eligible for 100 percent Federal matching funds. In proposing this methodology, we realize there may be multiple ways to achieve implementation and specifically request comments on this portion of the proposed rule.

To be clear, we are proposing that States would be required to submit the methodology they intend to use to identify the increment of the capitation payment attributable to increased provider rates to CMS for approval prior to the beginning of CY 2013. Further, we propose that, absent approval of its methodology from CMS, States would not be able to claim the enhanced Federal match for capitation payments to managed care plans.

This proposal was developed with input from States. During a January 27, 2011 all-State call specific to the impact of the amended section 1932(f) of the Act on managed care, States reported that the amount and type of data managed care plans report to them varies greatly both across and within States. States expressed the need to be able to identify the rate differential for the purpose of claiming 100 percent FFP and to do so in a manner that is reasonable and documented. We are seeking additional comments on how States might best meet these requirements.

B. Vaccine Administration Under the Vaccines for Children (VFC) Program

1. General Statement

At this time, we are proposing to add 42 CFR part 441 subpart K to codify the requirements of the Vaccines for Children Program. The general requirements of the VFC program will be found at § 441.510, and state that federally-purchased vaccines under the VFC Program are made available to children who are 18 years of age or younger and who are any of the following:

• Eligible for Medicaid.

• Not insured.

• Not insured for the vaccine and who are administered pediatric vaccines by a federally-qualified health center (FQHC) or rural health clinic (RHC).

• An Indian, as defined in section 4 of the Indian Health Care Improvement Act.

Under the VFC program, vaccines must be administered by program-registered providers. Section 1928(c) of the Act defines a program-registered provider as any health care provider that—

• Is licensed or authorized to administer pediatric vaccines under the law of the State in which the administration occurs without regard to whether or not the provider is a Medicaid-participating provider.

• Submits to the State an executed provider agreement in the form and manner specified by the Secretary.

• Has not been found, by the Secretary or the State to have violated the provider agreement or other applicable requirements established by the Secretary or the State.

Section 1928 of the Act requires each State to establish a VFC Program (which may be administered by the State Department of Health) and include this program in the State plan (§ 441.505) under which certain specified groups of children are entitled to receive qualified pediatric immunizations without charge for the cost of the vaccine.

In the October 3, 1994 **Federal Register**, we published a notice with comment period entitled, ''Charges for Vaccine Administration Under the Vaccines for Children (VFC) Program'' (59 FR 50235) (hereinafter referred to as the ''October 1994 VFC notice'') that set forth, by State, the interim regional maximum charges for the VFC program. These charges represented the maximum amount that a provider in a State could charge for the administration of qualified pediatric vaccines to federally vaccine-eligible children under the VFC Program. This proposed rule would announce updates to those fees for use on an interim basis. This is the first proposed update of the interim regional maximum administration fees since 1994. We received comments in response to the October 1994 VFC notice and we have reviewed them. We expect to address those comments in a separate document. We will respond to public comments provided in response to this proposed rule. We are interested in receiving comments on this proposed rule and suggestions for potential updates that could be made to the administration fees to ensure that the VFC regional

maximum rates are increased to reflect a more current cost of vaccine administration. As discussed in the October 1994 VFC notice, the interim maximum administration fees apply to all VFC program-registered providers that administer pediatric vaccines to federally vaccine-eligible children. The fees do not apply to children receiving free vaccines under State purchase programs or any other arrangement.

In accordance with section 1928(c)(2)(C)(ii) of the Act, we are proposing § 441.500 to state that physicians participating in the VFC program can charge federally vaccine-eligible children who are not enrolled in Medicaid the maximum administration fee (if that fee reflects the provider's cost of administration) regardless of whether the State has established a lower administration fee under the Medicaid program. Families of children who are enrolled in the VFC program because they are either uninsured or do not have insurance that covers vaccines would be impacted by this proposed regulation. Providers can bill the families of those children at the State's regional maximum rate for the administration of a vaccine. Therefore, if the proposed updated rates were to become effective, those families could be billed at the published rate for that State. However, section 1928(c)(2)(B)(iii) of the Social Security Act says that ''[t]he provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parent to pay an administration fee.'' A recent survey of providers participating in VFC shows that approximately 37 percent of those providers actually charge the State's maximum administration fee to families of children who are uninsured or who do not have insurance that covers vaccines. The remaining 61 percent of providers surveyed either write off the charge or charge a lesser amount. We solicit comments specifically on the impact of the increased fees on uninsured and underinsured VFC-eligible children. However, as discussed in the October 1994 VFC notice, and as proposed in new § 441.515(e), there would be no Federal Medicaid matching funds available for administration since these children are not eligible for Medicaid. Although the cost of the vaccines for the VFC program is funded under Title XIX of the Act, Medicaid will not pay for the administration of vaccines provided to children under the VFC program who are not Medicaid-eligible. A provider may only bill Medicaid for the administration of a vaccine if the child is eligible under Medicaid.

2. Methodology Used To Establish Administration Charges

In 1994, to obtain national average rates for the administration of vaccines, we contracted with the American Academy of Pediatrics (AAP) to purchase data on the normal fee charged by its members for administering the vaccines covered by this program. This was because there was no reliable data available on physicians' actual cost that would provide a valid base for setting these maximum charges on a nationwide scale. The final national average administration charge we obtained from the AAP was $15.09. The national average was then adjusted for regional variations, using indices established for the MPFS.

Before the publication of this proposed rule, we attempted to determine the availability of Medicaid cost data; however, just as in 1994, there is no data readily available on physician's actual costs that would provide a valid basis for recalculating these maximum fees. Therefore, in § 441.515, we are proposing to update the maximum administration fees based on the data and formula established in the October 1994 VFC notice. We continue to believe, given the nature of the program and the requirements applicable to participating providers, that charge data, adjusted for regional variations, is a reasonable proxy for calculating these maximum fees. To adjust the administration charge of $15.09 for inflation, we are proposing to use the Medicare Economic Index (MEI), which is a price index that is used by CMS to update Medicare physician payments. We are proposing to use the MEI because: (1) It reflects input price inflation faced by physicians inclusive of the time period when the national average was established in 1994, and (2) we believe that input prices associated with this specific type of physician-provided service are consistent with overall input prices. The MEI was most recently updated at the end of 2011 (76 FR 73275 through 73276, November 28, 2011). Therefore, we have calculated the proposed update based on the MEI up through and including CY 2012. Using that index, we have determined that the updated national average administration charge would be $21.80.

As in the October 1994 VFC notice, we would adjust the national average for regional variations, using indices established for the MPFS. The national average was weighted by the geographic adjustment factors (GAF), which reflects a weighted sum of the three geographic practice cost indexes (GPCIs) (work, practice expense, and malpractice insurance) for a given Medicare PFS locality.

The GAF is a proxy for differences in the cost of operating a medical practice among various geographic areas, and is used as a comparison among Medicare PFS localities (73 FR 69726, 69740 November 19, 2008). Consistent with the methodology in the October 1994 VFC notice, when there was more than one GAF per State, we would select the highest GAF within the State and use that GAF to adjust the average national vaccination administration charge for the entire State to assure that administration charges would fall within our established maximum rates.

The MPFS localities (and corresponding GAFs) are grouped by State and sub-State areas. As discussed in the October 1994 VFC notice, we developed the regional maximum charges for each ''State'' because the geographic area of a State is clearly identifiable by boundary lines recognized nationwide, as opposed to a sub-State area. In this proposed rule, we see no reason to change that interpretation.

We are also proposing to revise the national average for each State to reflect the fully implemented sixth comprehensive update to the MPFS GPCIs and updated GAFs. For more information on the methodology used for the most recent GPCI update, we refer readers to the CY 2012 MPFS final rule with comment period (76 FR 73026 through 73474). Consistent with that rule, the cost share weights for determining the GAF equation are 48.266 percent for physician work, 47.439 percent for practice expense, and 4.295 percent for malpractice insurance.

We derived the proposed interim amounts specified in the chart under section II of this proposed rule as the maximum allowable charges for the administration of qualified pediatric vaccines for each State on the basis of the formula: National charge data × updated GAFs = maximum VFC fee. (See Table 1.)

TABLE 1—EXAMPLE OF THE APPLICATION OF THE FORMULA FOR OHIO

Average national administration charge = $21.80.
Work expense = 0.998; practice expense = 0.927.
Malpractice expense = 1.24.
Using Medicare weights to weigh components of—
Work expense = 48.266 percent.
Practice expense = 47.439 percent.
Malpractice expense = 4.295 percent.
Calculation:
Work expense: 0.998 × 48.266 percent = 0.482.
Practice expense: 0.927 × 47.439 percent = 0.439.
Malpractice expense: 1.24 × 4.295 percent = 0.053.
Total expense = 0.975.
Ohio's updated maximum fee for administration of the vaccine is: $21.80 × 0.975 = $21.25.

The maximum updated administration fee would be effective with the publication of a final notice or regulation. We request comments on the methodology used to calculate this administration fee update and will consider revisions to the regional maximum fees in response to public comments. The proposed updated maximum fees are set forth in Table 2.

TABLE 2—REGIONAL MAXIMUM ADMINISTRATION FEE BY STATE

State	Current regional maximum fee	Updated regional maximum fee
Alabama	$14.26	$19.79
Alaska	17.54	27.44
Arizona	15.43	21.33
Arkansas	13.30	19.54
California	17.55	26.03
Colorado	14.74	21.68
Connecticut	16.56	23.41
Delaware	16.55	22.07
District of Columbia	15.13	24.48
Florida	16.06	24.01
Georgia	14.81	21.93
Guam		23.11
Hawaii	15.71	23.11
Idaho	14.34	20.13
Illinois	16.79	23.87
Indiana	14.47	20.32
Iowa	14.58	19.68
Kansas	14.80	20.26
Kentucky	14.17	19.93
Louisiana	15.22	21.30
Maine	14.37	21.58
Maryland	15.49	23.28
Massachusetts	15.78	23.29
Michigan	16.75	23.03
Minnesota	14.69	21.22
Mississippi	13.92	19.79
Missouri	15.07	21.53
Montana	14.13	21.32
Nebraska	13.58	19.82
Nevada	16.13	22.57
New Hampshire	14.51	22.02
New Jersey	16.34	24.23
New Mexico	14.28	20.80
New York	17.85	25.10
North Carolina	13.71	20.45
North Dakota	13.90	20.99
Ohio	14.67	21.25
Oklahoma	13.89	19.58
Oregon	15.19	21.96
Pennsylvania	15.76	23.14
Puerto Rico	12.24	16.80
Rhode Island	14.93	22.69
South Carolina	13.62	20.16
South Dakota	13.56	20.73
Tennessee	13.70	20.00
Texas	14.85	22.06
Utah	14.52	20.72
Vermont	13.86	21.22

TABLE 2—REGIONAL MAXIMUM ADMINISTRATION FEE BY STATE—Continued

State	Current regional maximum fee	Updated regional maximum fee
Virginia	14.71	21.24
Virgin Islands	15.09	21.81
Washington	15.60	23.44
West Virginia	14.49	19.85
Wisconsin	15.02	20.83
Wyoming	14.31	21.72

As noted in the October 1994 VFC notice, these fees are intended as guidance for Universal Purchase States (that is, where the vaccines are purchased by the State for all children in the State). These States may use the maximum charges listed or develop their own maximum fees.

In addition, as stated in the October 1994 VFC notice, State Medicaid agencies would not be obligated to set the Medicaid payment for vaccine administration at the level of the maximum fees set forth in this proposed rule. Therefore, if these proposed maximum fees were to go into effect, the amount that a State pays a provider under the Medicaid program would not increase unless a State were to submit a SPA to CMS that increases the rate. In accordance with sections 1902(a)(30) and 1928(c)(2)(C)(ii) of the Act, States have the flexibility to set their payment rates at a lower level than the State's regional maximum fee. State Medicaid agencies typically take a variety of factors into consideration when setting payment rates, including the need to assure adequate participation by providers.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The salary estimates include the cost of fringe benefits, calculated at approximately 35 percent of salary, which is based on the June 2011 Employer Costs for Employee Compensation report by the Bureau.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs):

A. ICR's Regarding Contract Requirements (§ 438.6)

In § 438.6(c)(3)(v) and (c)(5)(vi), States would be required to implement managed care contracts for payment to a MCO, PIPH or PAHP to comply with the requirements at section 1202 of the HCERA. There is a one-time burden to the State for amending such contracts for the following provisions: (1) To assure that the level of payment is consistent with part 447, subpart G; (2) to assure that the specified physicians (whether directly or through a capitated arrangement) receive an amount at least equal to the amount set for and required under part 447; and (3) to assure that the State receive documentation regarding those payments.

The burden associated with the requirements under § 438.6(c)(3)(v) and (c)(5)(vi) is the time and effort it would take each of the 35 State Medicaid programs with managed care plan payments and the District of Columbia (36 total respondents) to amend an average of three managed care contracts. We estimate it will take three hours to complete this task per contract at an estimated cost of $441.63 per respondent ($49.07/hr × 3 hr × 3 contracts) or $15,898.68 total ($441.63 per respondent × 36 respondents). In deriving this figure, we used a labor rate of $49.07/hr for a State's management, professional and related staff to amend each contract.

B. ICR's Regarding Provider Agreements (§ 441.505(b))

This requirement is exempt from OMB review and approval since we expect to receive fewer than 10 submissions (annually) from providers, if any. The requirement that providers must have provider agreements in place in order to participate in the VFC program has been in effect since the program was implemented in 1994. The provision in this regulation is merely codifying the requirement and no further action is necessary in regard to providers who are currently participating in the VFC program.

C. ICR's Regarding State Plan Amendments for the Vaccines for Children Program (§§ 441.510 and 441.515(d))

This requirement is exempt from the OMB review process as we expect to receive fewer than 10 submissions from States. The requirement that a State submit a State plan was a requirement when the VFC program was first established in 1994, and all States submitted State Plans at that time. A State now only submits a State plan amendment related to the VFC program when it makes a change to the State's administration fee. In 2011, only two States submitted State plans that made changes to the State's administration fee under the VFC program. Even with the publication of the updated fee schedule, we do not anticipate that many States will make changes to their State's administration fee.

D. ICR's Regarding Eligible Services (§ 447.400(a))

In § 447.400(a), States would be required to ensure that physicians identify their specialty to the Medicaid agency before an increased payment is made. Initial identification may be made by self-attestation, but for program integrity purposes the State will be required to verify the physician's claimed specialty status by reviewing the Board certification status of the physician, or reviewing the physician's practice characteristics, before paying for services at the Medicare rate.

The burden associated with the requirements under § 447.400(a) is the time and effort it would take each of the 50 Medicaid Programs and the District of Columbia (51 total respondents) to establish that a physician is qualified, either through Board certification or a supporting history of codes billed, to receive payment under section 1202 of the HCERA. We estimate that it will take 0.5 hours to determine whether a physician may receive payment under section 1202 of the HCERA. We used data from the Medicaid Statistical Information System (MSIS) to identify the number of physicians claiming for the E&M codes specified in this regulation during the fourth quarter of FY 2008 and FY 2009 (the most recent data available). Based on that data, there is an average of 2,245 physicians per State who currently bill, but whose eligibility for increased payment will need to be verified by the Medicaid agency. We increased this number by 10 percent to account for participation by new physicians for a total of 2,470 physicians.

We used the following hourly labor rates and estimated the time to complete each task: 0.5 hours for a State's Medicaid office and support staff working in the medical billing area to retrieve and assess claims for an individual physician; or 0.5 hours for administrative staff to review the Board certification status of a physician. Costs associated with these staff are reported at a cost of $14.12 for each half-hour derived from $28.24/hr each and 2,470 physicians for an estimated cost of $14.12 per response or $34,876.40 (total).

E. ICR's Regarding State Plan Requirements (§ 447.410)

In § 447.410, States would be required to submit a SPA to reflect the fee schedule rate increases for eligible primary care physicians under section 1902(a)(13)(C) of the Act. The purpose of this proposed requirement is to assure that when States make the increased reimbursement to providers, they have State Plan authority to do so and they have notified providers of the change in reimbursement as required by Federal regulations.

The burden associated with the one-time requirement under § 447.410 is the time and effort it would take each of the 50 State Medicaid Programs and the District of Columbia (51 total respondents) to modify the Medicaid State plan to reflect payment consistent with the requirements in section 1902(a)(13)(C) of the Act. This will require the preparation and submission of a SPA. We estimate that it will take State staff working 4 hours to complete all of the tasks associated with the preparation of an SPA. The estimated cost is $107.13 ($35.71/hr × 3 hr) per State or $5,463.63 total ($107.13 * 51) for tasks completed by non-management staff working on SPA preparation. We estimate that this task will also require 1 hour for State-employed legal staff at $49.07/hr or $49.07 (per response) for a total of $2,502.57 ($49.07 × 51). The combined total for cost associated with SPA preparation, including non-legal and legal staff employed by the State, is $7,966.20 ($5,463.63 + $2,502.57).

F. ICR's Regarding Additional Requirements (Methodology To Identify Rate Differential) for FFP for Managed Care Payments (§ 438.804(a)(2) and (3))

In § 438.804(a)(3), States would be required to submit the methodology they intend to use to identify the rate differential for managed care payments to CMS for approval 6 months prior to the beginning of CY 2013. Further, we propose that, absent approval from CMS, States would not be able to claim the enhanced Federal match for managed care payments.

The burden associated with the requirements under § 438.804(a)(2) and (3) is the time and effort it would take each of the 35 State Medicaid Programs with managed care plan payments and the District of Columbia (36 total respondents) to develop a methodology for the identification of payment made for primary care services through managed care contracts eligible for 100 percent Federal matching funds. This task will involve a one-time effort on the part of financial, legal and information technology staff. We estimate that it will take 14 hours per respondent at a cost of $637.42 to develop the identification methodology at a total cost of $22,947.12 (36 × $637.42). In deriving these figures, we used the following hourly labor rates and estimated the time to complete this task: $49.07/hr and 2 hours for legal staff to review the methodology for compliance with the statute ($98.14); $48.09/hr and 8 hours for managerial staff to assess the feasibility of implementing the methodology ($384.72); and $38.64/hr and 4 hours for information technology/public administration staff to assess the feasibility of the methodology ($154.56).

TABLE 3—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($)
§ 438.6(c)(3)(v) and (c)(5)(vi)	36	108	3	324	15,898.68	15,898.68
§ 447.400(a)	51	2,470	.50	1,235	34,876.40	34,876.40
§ 447.410	51	51	4	204	7,966.20	7,966.20
§ 438.804(a)(2) and (3)	36	36	14	504	22,947.12	22,947.12
Total				2,267	81,688.40	81,688.40

Note 1: All of the proposed collections are new. Therefore, OMB control numbers have not been assigned and the control number column has been omitted from the table.

Note 2: There are no capital or maintenance costs incurred by any of the proposed collections. Therefore, the capitol cost column has been omitted from the table.

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access our Web site at *http://www.cms.hhs.gov/Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you comment on these information collection and

recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, (CMS–2370–P) Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980; Pub. L. 96–354) (RFA), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that, to the best of our ability, presents the costs and benefits of the rulemaking. We solicit comment on the RIA analysis provided. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. This rule does not contain mandates that will impose spending costs on State governments in the aggregate of $139 million. The cost for increasing payment for primary care services in CYs 2013 and 2014 will be borne by the Federal government, which will provide 100 percent matching funds equal to the difference between the Medicaid State plan rate in effect July 1, 2009 and the Medicare rate implemented in CY 2013 and 2014, or the rate using the CY 2009 CF, if higher. Section 1202 of the HCERA requires higher payment to physicians for primary care services but does not impose increased costs on States. For the provisions associated with the charges for vaccine administration under the VFC program, the proposals will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As indicated, this proposed rule will not have a substantial effect on State and local governments.

B. Statement of Need

This proposed rule implements section 1202 of the HCERA requiring payment by State Medicaid agencies of at least the Medicare rates in effect in CYs 2013 and 2014 or, if higher, the rate using the CY 2009 CF for primary care services furnished by a physician with a specialty designation of family medicine, general internal medicine, or pediatric medicine. Also, this proposed rule implements the statutory payment provisions uniformly across all States, defines, for purposes of enhanced Federal match, eligible primary care physicians, identifies eligible primary care services, and specifies how the increased payment should be calculated. Finally, this proposed rule provides general guidelines for implementing the increased payment for primary care services delivered by managed care plans.

C. Overall Impact

The aggregate economic impact of this proposed rule is an estimated $5.52 billion in CY 2013 and $5.66 billion in CY 2014. In CY 2013, the Federal cost is approximately $5.74 billion with $225 million in State savings. In CY 2014, the Federal cost is approximately $5.96 billion with $300 million in State savings. The State savings are derived from the projected increases in reimbursement rates expected to occur prior to passage of this legislation between years 2009 and 2013 through 2014, which will now be paid for by the Federal government. Absent the legislation, the projected increases in the reimbursement rates would be split between the Federal government and States. This aggregate economic impact estimate includes the requirement that States reimburse specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum during CYs 2013 and 2014, which is estimated at $970 million in Federal costs. The Federal costs for funding that increase, in State payments during CYs 2013 and 2014, are estimated at $490 million and $480 million, respectively.

Overall, the estimated economic impacts are a result of this proposed rule providing States the ability to increase payment for primary care services without incurring additional costs. We anticipate higher payment will result in greater participation by primary care physicians, including primary care subspecialists, in Medicaid thereby helping to promote overall access to care. At this time it is not known whether States will be willing or have the ability to sustain this level of payment to providers beyond CY 2014. For managed care plans, this proposed rule would require documentation of the primary care services that are provided in order for States to claim 100 percent FFP. Currently, many States do not receive complete data on individual services provided by managed care plans. We believe, as result of this proposed rule, there will be improved documentation and reporting of primary care services provided by managed care plans. This, in turn, may serve to inform future managed care rate setting.

D. Detailed Economic Analysis

1. Anticipated Effects on Medicaid Recipients

We anticipate this proposed rule will have a positive effect on Medicaid recipients by increasing the availability of services through financial incentives to primary care physicians. The exact number of beneficiaries that will benefit

is not known, however, we believe it will be substantial because this rule directly affects payment for a type of service which is a key component of the Medicaid program. Additionally, we believe primary care physicians will be encouraged to accept more Medicaid beneficiaries into their practices as a result of increased payment.

We believe that this regulation will positively affect the availability of vaccination services as well. Currently, only 5 States reimburse the regional maximum for vaccine administration set by the VFC program. This proposed rule would require States to reimburse specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum during CYs 2013 and 2014.

Finally, this rule will positively affect patients who are dually eligible for benefits under the Medicare and Medicaid programs by increasing payment to physicians who serve this population. Specifically, Medicaid will pay higher amounts to providers. We anticipate that increased payment will promote greater access to primary care services for dually eligible beneficiaries.

2. Anticipated Effects on Other Providers

We anticipate this proposed rule would increase physician participation in Medicaid as most States reimburse physicians at well below the Medicare rates. Recently, as States have experienced budgetary constraints, they have sought to address this by reducing payments to providers, including physicians. This proposed rule would ensure that in CYs 2013 and 2014, physicians receive the higher Medicare rate for the specified primary care services.

In addition, this proposed rule would impact States and providers who provide immunizations under the Medicaid program because it will require that such providers be reimbursed at the lesser of the 2013 or 2014 Medicare rate or the Regional Maximum VFC Administration Fee in CYs 2013 and 2014. This rule also raises the maximum rate that States could pay providers for the administration of vaccines under the VFC program in subsequent years. The proposed updated Regional Maximum Administration Fees included in this proposed rule are the maximum amounts that a State could choose to reimburse a provider for the administration of a vaccine under the VFC program after the provisions of the primary care payment increase expire at the end of CY 2014. States have the flexibility to set the rate that they will reimburse providers, and can therefore choose to set it at the State's regional maximum fee or at any other amount below the regional maximum amount. It is not expected that all States will choose to implement the increase.

The impact of this proposed rule on the Federal Government is therefore connected to States decisions as to whether to increase the amount that they pay providers for the administration of vaccines after CY 2014. That is, if no States choose to increase the administration fee for providers, there would be no additional costs incurred by the Federal Government.

The same is true for States. There would be no impact of this proposed rule on a State unless the State chooses to increase the amount that it reimburses providers for the administration of vaccines under the VFC program.

Children enrolled in the VFC program who are Medicaid eligible would not incur any additional costs as a result of this proposed rule as there are no out-of-pocket expenses related to the VFC program for Medicaid eligible children.

Families of children who are enrolled in the VFC program because they are either uninsured or do not have insurance that covers vaccines would be impacted by this proposed regulation. The Affordable Care Act does not make any changes to the VFC program and therefore uninsured and underinsured individuals receiving vaccines through the VFC program will continue to pay a single administration fee for any vaccine provided. The provider will also receive a single administration fee for any vaccine provided, regardless of the number of vaccine/toxoid components, and will not receive the Medicare administration rate for those services. Providers can bill the families of those children at the State's regional maximum rate for the administration of a vaccine. As a result, if the proposed updated rates were to become effective, those families could be billed at the published rate for that State. However, section 1928(c)(2)(B)(iii) of the Social Security Act says that ''[t]he provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parent to pay an administration fee.''

Therefore, providers could benefit from the proposed regulation as they could charge and receive the State's regional maximum rate for their patients who are enrolled in the VFC program because they are either uninsured or do not have insurance that covers immunizations. A provider would not receive an increased administration fee for Medicaid-eligible children unless a State chose to increase the amount that it pays providers under the Medicaid program.

3. Anticipated Effects on the Medicaid Program Expenditures

Table 4 provides estimates of the anticipated Medicaid program expenditures associated with increasing payment for primary care services. CMS' Office of the Actuary (OACT) developed estimates for the impact of this section of the Affordable Care Act, which were initially published in April 2010, (*https://www.cms.gov/ActuarialStudies/downloads/PPACA_2010-04-22.pdf*). Initially, projections of Medicaid spending on primary care physician services by FFS Medicaid and Medicaid managed care plans were created. For this, OACT developed assumptions of (1) what share of Medicaid physician spending was for primary care and (2) what share of managed care spending was for physician services, relying on several studies on physician service utilization and expenditures. OACT then projected spending for 2013 and 2014 based on the projections of Medicaid physician spending in the President's Fiscal Year 2010 Budget Mid-Session Review. To determine the impact of using Medicare physician payment rates for Medicaid payments, OACT compared the ratio of Medicaid rates to Medicare rates, based on a study of Medicare and Medicaid physician payment rates across all States. Finally, OACT projected growth in Medicaid physician payments and the rates prescribed by section 1202 of the HCERA, based on Medicare payment rates; these estimates were revised to incorporate the actual CY 2011 CF, (75 FR 73169). OACT assumed that physician services covered by Medicaid would increase over 2013 and 2014 as a result of higher payments and expected increases in physician participation in Medicaid. Additionally, these changes were estimated to result in a slight decrease to projected State spending as future projected Medicaid payment rate increases would be covered by increased Federal matching funds in 2013 and 2014. The studies and data sources used for developing these estimates included: S. Zuckerman, ''Trends in Medicaid Physician Fees, 2003–2008,'' *Health Affairs,* 28 April 2009; the American Medical Association; the Medical Group Management Association; and the Bureau of Labor Statistics.

TABLE 4—FEDERAL AND STATE MEDICAID IMPACTS FOR PAYMENT INCREASES TO PRIMARY CARE PROVIDERS DURING CALENDAR YEARS 2013 THROUGH 2014

[Millions of 2012 dollars]

	CY 2013	CY 2014
Federal Share *	$5,740	$5,960
State Share	−225	−300
Total	5,515	5,660

* Federal cost estimates reflect the additional $490 million and $480 million in CYs 2013 and 2014, respectively, as a result of States reimbursing specified physicians for vaccine administration at the lesser of the Medicare rate or the VFC regional maximum.

The Medicare payment rates used in this estimate were the actual 2009 MPFS and the current statute projections of the CYs 2013 and 2014 MPFS.

In addition, it should be noted that these estimates are based on the current statute which includes a significant projected reduction to payment rates in the CY 2013 MPFS under the Sustainable Growth Rate (SGR) formula. Every year since 2003, the Congress has passed legislation overriding projected cuts that otherwise would have resulted from the SGR formula. Furthermore, it is possible that the Congress may enact legislation that averts the currently projected reduction in MPFS rates for 2013 which would affect the CYs 2013, and 2014 rates that are being used to estimate the payment impacts in this rule. Consequently, if the Congress enacts legislation resulting in increased payment rates to replace the payment rate reduction called for under the SGR formula in CYs 2013, and 2014, and in turn the CYs 2013 or 2014 rates exceed the rates calculated using the CY 2009 CF, then this would result in higher costs for the CYs 2013 and 2014 Medicaid physician payments presented in this rule. Additionally, other changes to the CF in these years may also affect the costs of this section. Therefore, currently it is not possible to accurately estimate the impact of these potential future changes, since definitive action, if any, by the Congress regarding the MPFS CF is unknown.

4. Anticipated Effects on States

The Federal government would provide 100 percent matching funds for the difference between the Medicaid State plan rate in effect July 1, 2009 and the Medicare rate in CYs 2013 and 2014 or the rate using the CY 2009 Medicare CF, if higher. Therefore, we believe this proposed rule would result in a positive effect on States, since it reduces their expenditures for primary care services. State savings are estimated at $225 million and $300 million in CYs 2013 and 2014, respectively. However, for Medicaid State plan rates below the 2009 level, States would be required to reimburse the non-Federal share of that portion, so as to return to the 2009 level of payment. We are unable to accurately quantify the impact of this effect on States, since there is not a precise relationship between any of the Medicaid State plan rates and the Medicare rates.

5. Anticipated Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organization, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business and having revenues of less than $7.0 million to $34.5 million in any 1 year. (For details, see the Small Business Administration's Table of Size Standards at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf*.) For purposes of the RFA, approximately 95 percent of physicians are considered to be small entities. Individuals and States are not included in the definition of a small entity.

We anticipate that this regulation would primarily impact individual physicians and State Medicaid agencies. This proposed rule requires States to increase payment for primary care services without incurring additional State cost. As previously noted, we anticipate that this higher payment would impact physicians by encouraging greater participation by primary care physicians, including primary care subspecialists, in Medicaid, thereby helping to promote overall access to care. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule would not have a significant impact on small rural hospitals because it only affects physicians. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that none of the provisions in this proposed rule would have a significant impact on the operations of a substantial number of small rural hospitals.

E. Alternatives Considered

This section provides an overview of the issues addressed in the proposed rule and the regulatory alternatives considered. In identifying the issues and developing alternatives, we consulted with States and other interested stakeholders such as primary care specialists and policy makers. We solicit comment on the assumptions and analyses presented in the Alternatives Considered section.

1. Eligible Providers

The statute specifies that increased payment may be made for primary care services furnished by a physician with a primary specialty designation of family medicine, general internal medicine or pediatric medicine. Because States have varying methods of identifying a physician's specialty this poses a challenge to the uniform implementation of the increased payment. Currently, there are no Federal requirements surrounding how States must enroll Medicaid providers. In this rule, we propose to use Board certification and a supporting history of codes billed in the absence of Board certification as a means of identifying eligible primary care physicians but seek comment on the time period from which claimed codes would be drawn. We considered permitting physicians to qualify for payment based solely on self attestation in the absence of Board certification but were concerned that without an objective measure, such as a supporting history of codes billed, certain physicians could be unfairly advantaged or disadvantaged in receiving the increased payment. We also believe that an objective measure is more supportive of program integrity.

This proposed rule clarifies that subspecialists related to the specialty designations identified in the statute would be eligible for payment. We considered extending eligibility for increased payment to only those physicians with a primary care specialty designation of family medicine, general internal medicine or pediatric medicine and not to subspecialists within those categories. However, through our engagement with the provider community we learned that pediatric subspecialists routinely deliver primary

care services. Therefore, we propose to make all subspecialists within the primary care specialties designated in the statute eligible for the enhanced payment. Due to the limited data available, including the lack of discrete data on physician specialty or subspecialty, we are unable to accurately estimate the impacts representing the exclusion of subspecialties relative to this proposed regulation. The analysis is further complicated by the observation that some types of subspecialists may provide a significant amount of primary care services, while other types of subspecialists may provide very little primary care services, thereby limiting any sound assumptions presented including the entailed impact modeling.

2. Payment Made Under the Physician Benefit as a Physician Service

This rule clarifies physician services to mean any service delivered under the physicians' services benefit at 1905(a)(5)(A) of the Act. First, we considered whether the statute limited increased payment to services provided only by physicians. In the Medicaid program, a significant proportion of primary care services are actually rendered by advance practice nurses, and other types of independently practicing non-physicians. We recognize the importance of these non-physician practitioners in the provision of primary care services in many States. However, section 1902(a)(13)(c) of the Act limits eligibility for higher payment to services provided by physicians. Next we considered whether the statute limited increased payment to services provided directly by physicians. Medicaid regulations at 42 CFR 440.50 define ''physician services'' as services provided by or under the personal supervision of a physician. Therefore, we concluded that, in light of the important role of these practitioners in delivering primary care to Medicaid beneficiaries and the regulatory definition of a ''physician service,'' those services delivered under the personal supervision of a specified primary care physician could qualify for the increased payment. This means that specified primary care services rendered by non physicians such as advanced practice nurses and other mid-level professionals qualify for payment when billed under the Medicaid enrollment number of any designated primary care specialist or subspecialist.

Due to the limited data available, we are unable to accurately estimate the impacts representing the inclusion of services provided by practitioners under the supervision of a physician. All such services are billed under the supervising physician's billing number and are reported as physician services to CMS making it impossible to determine the impact of this proposal.

We also considered whether services provided by physicians in settings such as FQHCs, RHCs, or clinics would be eligible for increased payment. In Medicaid ''physician services'' is a distinct benefit from other benefits such as the FQHC, RHC or clinic benefits. We believe that the statute limits payment to physicians who, if Medicare providers, would be reimbursed using the MPFS. The MPFS is not used to reimburse physicians in settings such as FQHCs and RHCs and we believe that enhanced payment should not be extended to physicians under other Medicaid benefit categories. Furthermore, the Medicaid statute already requires that FQHCs and RHCs be reimbursed at cost.

We estimate that the inclusion of services provided by physicians in settings such as FQHCs, RHCs, or clinics for increased payment would result in an aggregate Federal cost of approximately $820 million for CYs 2013 and 2014. The limitations of this impact estimate to more accurately reflect clinic participation include, (1) determining whether the services provided in the various clinic types are in fact performed by a qualifying physician, and (2) determining the direct link between Medicaid clinic payment rates, as they vary substantially across codes and states, and Medicaid physician rates.

3. Eligible E&M Services

The statute requires enhanced payment for E&M services/codes. The proposed rule specifies the E&M Codes eligible for the increased payment. They include all primary care E&M codes, including some codes not recognized for payment by Medicare. Because the statute requires payment at the Medicare rate, we considered not extending the requirement for increased payment to codes not reimbursed by Medicare. However, many of those codes represent services provided to children. While Medicare covers relatively few children, payments for services provided to children constitute a larger proportion of Medicaid expenditures. We therefore include these additional codes because they represent core primary care services that are important to the Medicaid program.

We estimate that approximately 6 to 7 percent of all expenditures on services eligible for the increased payment rates are for services not covered by Medicare. Furthermore, we believe that a corresponding amount of the Federal costs associated with this proposed regulation would be related to these services, reflecting an impact range of $670 million to $780 million over the two CYs 2013 and 2014.

The eligible codes are listed in the regulatory text. We propose to set rates for codes not covered by Medicare based on a calculation of the CF and RVUs that are published by CMS. We establish RVUs based on recommendations from the AMA RUC and clinical review by Medicare. We considered setting rates for these codes by looking at rates paid by Medicare for comparable services. However, each code is designed to represent a distinct service and we could not find codes that we were comfortable substituting on a one for one basis for purposes of rate setting. We seek comment on the proposed rate setting methodology for codes not reimbursed by Medicare.

4. Eligible Vaccine Administration Services

The statute specifies payment at the CY 2013 and 2014 Medicare rate for certain vaccine administration billing codes or their successor codes. A State may receive 100 percent FMAP for the difference between the Medicaid rate as of July 1, 2009 and the Medicare rates in CYs 2013 and 2014 or the rate using the CY 2009 CF, if higher. In 2011, the coding structure for vaccine administration changed such that two codes replaced four of the specified codes. Moreover, the four deleted codes represented vaccine administrations by various routes (e.g., intranasal vs. injectable) to children under 8. However, new code 90460 represents the initial vaccine/toxoid administered through all routes to children under 18 while code 90461 represents payment for additional vaccines/toxoids administered. This rule proposes a method for imputing a vaccine administration rate in 2009 for code 90460. The proposed 2009 would equal the average payment amount weighted by volume of the four codes used in 2009. The 2009 value for code 90461 would be $0, since there was no payment for additional vaccines/toxoids prior to 2011. We seek comment from States and other stakeholders on this proposed methodology.

In 2009, approximately 20 States used a bundled rate to reimburse vaccines and vaccine administration, complicating the identification of the rate differential. This rule clarifies that, for any bundled rate payments such as this, States must correctly identify the rate differential for the included primary care service only (in this case,

vaccine administration). We added this provision in the interest of promoting program payment integrity but defer to the States to develop a methodology.

In this rule, we propose that providers administering vaccines under the VFC program be reimbursed the lesser of the Medicare rates in 2013 or 2014 or the Regional Maximum Administration Fee per vaccine, with no payment for additional vaccine/toxoid components. We considered proposing that States be required to pay VFC physicians for vaccine administration associated with the VFC program the amounts required by sections 1902(a)(13)(c) and 1932(f) of the Act, notwithstanding limitations on provider billing for vaccine administration under the VFC program. Free vaccine is made available through the VFC program to ''program registered providers'' who have entered into a VFC provider agreement. Under section 1928(c)(2)(C)(ii) of the Act, one of the requirements of that agreement is that program registered providers limit administration fees to an amount that ''does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration).''

This rule would not have changed the statutory requirement in section 1928(c)(2)(C) of the Act that a qualified physician administering a vaccine obtained from the VFC program is limited under the VFC provider agreement to charging an amount for vaccine administration that is no more than the VFC maximum allowable charge. However, we considered proposing that States comply with the requirements of sections 1902(a)(13)(c) and 1932(f) of the Act and pay the designated Medicare amount despite the fact that this amount might have been higher than the amount that was billed by the provider. To meet this requirement we considered proposing that States re-price vaccine administration billing codes, resulting in payment equal to the applicable Medicare-based rate.

We considered this alternative to fully reflect the requirement in section 1202 of the HCERA that Medicaid payment for primary care services be not less than the MPFS payment rate. While Medicare provider payment is limited to the lesser of provider charges or the fee schedule amount, we considered that allowing provider payment to exceed provider charges in this instance could be allowable in order to achieve the objectives of sections 1902(a)(13)(c) and 1932(f) of the Act. We also considered proposing that VFC providers account for the payment in excess of the billed amount as a Medicaid receipt for vaccine administration and that they ensure that it was not considered as an increase in the billed amount, or as a credit toward either the beneficiary account or toward payment for other services.

The primary benefit of this alternative is higher reimbursement for vaccine administration fees associated with the VFC program. Although the VFC ceilings have not been modified since 1994, the majority of States have paid for vaccine administrations at rates well below the ceilings. For example, California's maximum rate was $17.55, but the State paid $9.00. Approximately five States reimbursed vaccine administration fees within close proximity to the ceiling. Medicare's 2011 reimbursement rate for the first vaccine was $23.10 and for subsequent vaccines was $11.55. Therefore, we believe that requiring VFC administrations be reimbursed at the Medicare rate will help to ensure adequate compensation for VFC providers. However, we were concerned about the potential Federal budget impact of this proposal, with initial estimates indicating a potential cost impact of approximately $970 million over CYs 2013 and 2014, and the administrative burden it would place on States to reprice claims for these services.

We also considered whether the requirements of the VFC statute preclude application of sections 1902(a)(13)(c) and 1932(f) of the Act to vaccine administration under the VFC program. However, this would mean that participating providers would be limited to the State-specific VFC rates in the Medicaid State plan as well as to payment per vaccine administered.

Another alternative was to require payment at the DHHS VFC regional maximum fee schedule amount but to also require reimbursement for each vaccine/toxoid administered. This would comply with VFC requirements that providers charge no more than the regional maximum amount, but would permit providers to benefit from the coding change that requires payment per vaccine/toxoid administered.

We recognize the complexity of the issues surrounding the interplay of the VFC statutory requirements and the requirements of the Affordable Care Act and specifically request comment on these proposals.

5. Method of Payment

Section 1902(a)(13)(C) of the Act requires payment in CYs 2013 and 2014 of the current Medicare rate, unless the rate set using the CY 2009 CF was higher. Historically, Medicare has issued multiple updates to its MPFS within a single year.

Based on input from States, and to assure the feasibility of implementation, we propose to permit States the option to either adopt the MPFS in effect at the beginning of CYs 2013 and 2014 or the rate using the CY 2009 CF, if higher or a methodology to update rates to reflect changes made my Medicare during the year. If the State chooses to reflect changes made by Medicare, the methodology for those updates must be specified. States would be required to use the MPFS applicable to the place of service and geographic location. We considered requiring States to make changes throughout the year, as Medicare changed its MPFS. However, our proposal to permit States to use a single version of the MPFS reflects extensive comment received from States concerned about balancing the need for administrative ease with meeting the requirements to make this payment.

We also propose that payment not be made inclusive of Medicare's incentive payment as authorized under section 5501(a) of the Affordable Care Act. We considered defining the Medicare ''rate'' as being inclusive of the incentive payments. However, the Medicare incentive payments are supplements made to specific providers based on total Medicare allowed charges and do not represent increases to the MPFS rates for specific CPT codes. Moreover, even if the same providers qualified for both the Medicare incentive payment and this Medicaid payment, it would be administratively difficult for State Medicaid agencies to determine the Medicare ''rate'' for purposes of the increased Medicaid payment since States do not have access to Medicare payment data.

For the purpose of identifying the differential between the Medicaid rate and the Medicare rate, this proposed rule would define the Medicaid ''rate'' under the approved Medicaid State plan as the final rate paid to a provider inclusive of all supplemental or enhanced payments made to that provider. For example, many States reimburse physicians affiliated with academic medical centers the Medicaid State plan rate plus a supplemental amount that together equal the average amount paid by commercial third party payers. Therefore, in calculating the rate differential, these States would determine the CY 2009 Medicaid rate inclusive of this type of supplemental payment. We considered not defining ''rate'' but, recognizing the wide variety of ways in which States characterize their payments, we chose to make this

clarification to promote uniform and fair implementation of this payment.

6. VFC Administration Fee Increase

We considered a number of options when determining to update the average national administration charge portion of the formula used to calculate the VFC administration fee. These options included using the Medicare Economic Index (MEI), Consumer Price Index (CPI) or the Gross Domestic Product Deflator. We have determined the best option is to utilize the MEI, which is a price index used by CMS to update Medicare physician payments. The MEI reflects input price inflation experienced by physicians inclusive of the time period when the national average was established in 1994. Therefore, we believe that input prices associated with this specific type of physician-provided service are consistent with overall input prices.

The overall economic impact, as a result of this proposed rule announcing updates to the regional maximum charges for the VFC program for use on an interim basis, is estimated at $75 million per year. The Federal cost of this total is approximately $45 million per year. These estimates assume that every State would increase its reimbursement rate to the new VFC maximum fee.

F. Accounting Statement and Table

As required by OMB's Circular A–4 (available at *http://www.whitehouse.gov/omb//circulars_a004_a-4/*), in Table 5 we have prepared an accounting statement illustrating the classification of the Federal and State expenditures associated with this proposed rule.

TABLE 5—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR PAYMENT INCREASES TO PRIMARY CARE PROVIDERS DURING CALENDAR YEARS 2013 THROUGH 2014

[Millions of 2012 dollars]

Category	Transfers		
Annualized monetized transfers	Discount rate		Period covered
	7%	3%	
Primary Estimate	$5,846	$5,848	CYs 2013–2014
From/To	Federal Government to Medicaid Providers.		
Primary Estimate	−$261	−$262	CYs 2013–2014
From/To	State Governments to Medicaid Providers.		

List of Subjects

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 438—MANAGED CARE

1. The authority citation for part 438 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 438.6 is amended by adding new paragraphs (c)(3)(v) and (c)(5)(vi) to read as follows:

§ 438.6 Contract requirements.

* * * * *

(c) * * *

(3) * * *

(v) For rates covering CYs 2013 and 2014, complying with minimum payment for physician services under paragraph (c)(5)(vi) of this section, and part 447, subpart G, of this chapter.

* * * * *

(5) * * *

(vi) For CYs 2013 and 2014, and payments to an MCO, PIHP or PAHP for primary care services furnished to enrollees under part 447, subpart G, of this chapter, the contract must require that the MCO, PIHP or PAHP meet the following requirements:

(A) Make payments to those specified physicians (whether directly or through a capitated arrangement) at least equal to the amounts set forth and required under part 447, subpart G, of this chapter.

(B) Provide sufficient documentation to the State, as determined by the State, regarding the amount provider payments increase as a result of meeting the requirement of paragraph (c)(5)(vi)(A) of this section.

* * * * *

3. Section 438.804 is added to read as follows:

§ 438.804 Primary care provider payment increases.

(a) For MCO, PIHP or PAHP contracts that cover calendar years 2013 and 2014, FFP is available at an enhanced rate of 100 percent for the portion of the expenditures for capitation payments made under those contracts to comply with the contractual requirement under § 438.6(c)(5)(vi) only if the following requirements are met:

(1) The State makes a reasonable estimate of the increased amounts paid for specified primary care services provided by eligible primary care physicians resulting from the contractual requirement under § 438.6(c)(5)(vi), based on information received from the managed care provider for services furnished as of July 1, 2009.

(2) The State develops a methodology for identifying the differential in payment between the provider payments that would have been made by the managed care provider on July 1, 2009 and the amount needed to comply with the contractual requirement under § 438.6(c)(5)(vi).

(3) The State must submit the methodology in paragraph (a)(2) of this section to CMS for approval before the beginning of CY 2013.

(b) [Reserved]

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

4. The authority citation of part 441 is revised to read as follows:

Authority: Secs. 1102, 1902, and 1928 of the Social Security Act (42 U.S.C. 1302).

5. Subpart K is added to read as follows:

Subpart K—Vaccines for Children Program

Sec.
441.500 Basis and purpose.
441.505 General requirements.
441.510 State plan requirements.
441.515 Administration fee requirements.

Subpart K—Vaccines for Children Program

§ 441.500 Basis and purpose.

This subpart implements sections 1902(a)(62) and 1928 of the Act by requiring States to provide for a program for the purchase and distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children.

§ 441.505 General requirements.

(a) Federally-purchased vaccines under the VFC Program are made available to children who are 18 years of age or younger and who are any of the following:

(1) Eligible for Medicaid.

(2) Not insured.

(3) Not insured with respect to the vaccine and who are administered pediatric vaccines by a federally qualified health center (FQHC) or rural health clinic.

(4) An Indian, as defined in section 4 of the Indian Health Care Improvement Act.

(b) Under the VFC program, vaccines must be administered by program-registered providers. Section 1928(c) of the Act defines a program-registered provider as any health care provider that meets the following requirements:

(1) Is licensed or authorized to administer pediatric vaccines under the law of the State in which the administration occurs without regard to whether or not the provider is a Medicaid-participating provider.

(2) Submits to the State an executed provider agreement in the form and manner specified by the Secretary.

(3) Has not been found, by the Secretary or the State to have violated the provider agreement or other applicable requirements established by the Secretary or the State.

§ 441.510 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of this subpart.

§ 441.515 Administration fee requirements.

(a) Under the VFC Program, a provider who administers a qualified pediatric vaccine to a federally vaccine-eligible child, may not impose a charge for the cost of the vaccine.

(1) A provider can impose a fee for the administration of a qualified pediatric vaccine as long as the fee does not exceed the costs of the administration (as determined by the Secretary based on actual regional costs for the administration).

(2) A provider may not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents or legal guardian to pay the administration fee.

(b) The Secretary must publish each State's regional maximum charge for the VFC program, which represents the maximum amount that a provider in a State could charge for the administration of qualified pediatric vaccines to federally vaccine-eligible children under the VFC program.

(c) An interim formula has been established for the calculation of a State's regional maximum administration fee. That formula is as follows: National charge data x updated geographic adjustment factors (GAFs) = maximum VFC fee.

(d) The Medicaid Agency must submit a State plan amendment that identifies the amount that the State will pay providers for the administration of a qualified pediatric vaccine to a Medicaid-eligible child under the VFC program. The amount identified by the State cannot exceed the State's regional maximum administration fee.

(e) Physicians participating in the VFC program can charge federally vaccine-eligible children who are not enrolled in Medicaid the maximum administration fee (if that fee reflects the provider's cost of administration) regardless of whether the State has established a lower administration fee under the Medicaid program. However, there would be no Federal Medicaid matching funds available for the administration since these children are not eligible for Medicaid.

PART 447—PAYMENTS FOR SERVICES

6. The authority citation for part 447 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

7. Subpart G is added to read as follows:

Subpart G—Payments for Primary Care Services Furnished by Physicians

Sec.
447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.
447.405 Amount of required minimum payments.
447.410 State plan requirements.
447.415 Availability of Federal financial participation (FFP).

Subpart G—Payments for Primary Care Services Furnished by Physicians

§ 447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.

(a) States pay for services furnished by a physician as defined in § 440.50 of this chapter, or under the personal supervision of a physician who self-attests to a specialty designation of family medicine, general internal medicine or pediatric medicine or a subspecialty recognized by the American Board of Medical Specialties and is verified by the Medicaid agency as meeting one of the following requirements:

(1) Is Board certified with such a specialty or subspecialty.

(2) Has furnished evaluation and management services and vaccine administration services under codes described in paragraph (b) of this section that equal at least 60 percent of the Medicaid codes billed during the most recently completed CY.

(3) For physicians who do not have 12 months of paid Medicaid claims history, data on codes billed must be reviewed from the date of enrollment through the end of the enrollment CY.

(b) Primary care services designated in the Healthcare Common Procedure Coding System (HCPCS) are as follows:

(1) Evaluation and Management (E&M) codes 99201 through 99499.

(2) Current Procedural Terminology (CPT) vaccine administration codes 90460, 90461, 90471, 90472, 90473 and 90474, or their successor codes.

§ 447.405 Amount of required minimum payments.

(a) For CYs 2013 and 2014, a State must pay for physician services described in § 447.400 based on the lesser of:

(1) The Medicare Part B fee schedule rate that is applicable to the site of service and geographic location of the service of, if there is no applicable rate the rate specified in a fee schedule established and announced by CMS (that is, the product of multiplying the

Medicare CF in effect at the beginning of CYs 2013 or 2014 (or the CY 2009 CF, if higher) and the CY 2013 and 2014 relative value units (RVUs).

(2) The provider's actual billed charge for the service.

(b) For vaccines provided under the Vaccines for Children Program in CYs 2013 and 2014, a State must pay the lesser of:

(1) The Regional Maximum Administration Fee; or,

(2) The Medicare fee schedule rate in CY 2013 or 2014 (or, if higher, the rate using the 2009 conversion factor and the 2013 and 2014 RVUs) for code 90460.

§ 447.410 State plan requirements.

The State must amend its plan to reflect the increase in fee schedule payments in CYs 2013 and 2014 unless, for each of the billing codes eligible for payment, the State currently reimburses at least as much as the higher of the CY 2013 and CY 2014 Medicare rate or the rate that would be derived using the CY 2009 conversion factor and the CY 2013 and 2014 Medicare relative value units (RVUs).

§ 447.415 Availability of Federal financial participation (FFP)

(a) For primary care services furnished by physicians specified in § 447.400, FFP will be available at the rate of 100 percent for the amount by which the payment required to comply with § 447.405 exceeds the Medicaid payment that would have been made under the approved State plan in effect on July 1, 2009.

(b) For purposes of calculating the payment that would have been made under the approved State plan in effect on July 1, 2009, the State must consider all supplemental and increased payments made for the individually billed codes, including any incentive payments and other supplemental payment in effect at that time.

(c) For vaccine administration, the State must impute the payment that would have been made under the approved Medicaid State plan in effect on July 1, 2009 by calculating the average payment for codes 90465, 90466, 90467 and 90468 weighted by volume.

(d) For any payment made under a bundled rate methodology, including bundled rates for vaccines and vaccine administration, the amount directly attributable to the applicable primary care service must be isolated for purposes of determining the availability of the 100 percent FFP rate.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.)

Dated: April 17, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 18, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–11421 Filed 5–9–12; 11:15 a.m.]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

[WO–300–L13100000.FJ0000]

RIN 1004–AE26

Oil and Gas; Well Stimulation, Including Hydraulic Fracturing, on Federal and Indian Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Land Management (BLM) is proposing a rule to regulate hydraulic fracturing on public land and Indian land. The rule would provide disclosure to the public of chemicals used in hydraulic fracturing on public land and Indian land, strengthen regulations related to well-bore integrity, and address issues related to flowback water. This rule is necessary to provide useful information to the public and to assure that hydraulic fracturing is conducted in a way that adequately protects the environment.

DATES: Send your comments on this proposed rule to the BLM on or before July 10, 2012. The BLM need not consider, or include in the administrative record for the final rule, comments that the BLM receives after the close of the comment period or comments delivered to an address other than those listed below (see **ADDRESSES**). If you wish to comment on the information collection requirements in this proposed rule, please note that the Office of Management and Budget (OMB) is required to make a decision concerning the collection of information contained in this proposed rule between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it by June 11, 2012.

ADDRESSES: *Mail:* U.S. Department of the Interior, Director (630), Bureau of Land Management, Mail Stop 2134 LM, 1849 C St. NW., Washington, DC 20240, Attention: 1004–AE26. *Personal or messenger delivery:* Bureau of Land Management, 20 M Street SE., Room 2134 LM, Attention: Regulatory Affairs, Washington, DC 20003. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions at this Web site.

Comments on the information collection requirement: *Fax:* Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, Desk Officer for the Department of the Interior, fax 202–395–5806. *Electronic mail: oira_docket@omb.eop.gov.* Please indicate ''Attention: OMB Control Number 1004–XXXX,'' regardless of the method used to submit comments on the information collection burdens. If you submit comments on the information collection burdens, please provide the BLM with a copy of your comments, at one of the addresses shown above.

FOR FURTHER INFORMATION CONTACT: Steven Wells, Division Chief, Fluid Minerals Division, 202–912–7143 for information regarding the substance of the rule or information about the BLM's Fluid Minerals Program. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

Executive Summary

''Hydraulic fracturing,'' a process used to stimulate production from oil and gas wells, has been a growing practice in recent years. Public awareness of fracturing has grown as new horizontal drilling technology has allowed increased access to shale oil and gas resources across the country, sometimes in areas that have not previously experienced significant oil and gas development. The extension of the practice has caused public concern about whether fracturing can allow or cause the contamination of underground water sources, whether the chemicals used in fracturing should be disclosed to the public, and whether there is adequate management of well integrity and the ''flowback'' fluids that return to the surface during and after fracturing operations.

The Bureau of Land Management (BLM) oversees approximately 700 million subsurface acres of Federal

mineral estate and 56 million subsurface acres of Indian mineral estate across the United States. The BLM proposes to modernize its management of well stimulation activities, including hydraulic fracturing, to ensure that fracturing operations conducted on the public mineral estate (including split estate where the Federal Government owns the subsurface mineral estate) follow certain best practices, including: (1) The public disclosure of chemicals used in hydraulic fracturing operations on Federal lands; (2) confirmation that wells used in fracturing operations meet appropriate construction standards; and (3) a requirement that operators put in place appropriate plans for managing flowback waters from fracturing operations.

The BLM proposes to apply the same rules and standards to Indian lands so that these lands and communities receive the same level of protection provided for public lands. Most of these requirements in this rule can be satisfied by submitting additional information during the process that the BLM currently applies to operators who are drilling on public or Indian lands. The proposed rule would require that disclosure of the chemicals used in the fracturing process be provided to the BLM after the fracturing operation is completed. This information is intended to be posted on a public web site, and the BLM is working with the Ground Water Protection Council to determine whether the disclosure can be integrated into the existing Web site known as FracFocus.org.

The BLM has developed the draft with an eye toward improving public awareness and oversight without introducing complicated new procedures or delays in the process of developing oil and gas resources on public and Indian lands. Some states have started requiring similar disclosures and oversight for oil and gas drilling operations under their own jurisdiction. This proposal seeks to create a consistent oversight and disclosure model that will work in concert with other regulators' requirements while protecting Federal and tribal interests and resources.

The BLM proposes these changes to existing well stimulation oversight partly in response to recommendations put forward by the Secretary of Energy's Energy Advisory Board in 2011. Also, current BLM regulations governing hydraulic fracturing operations on public lands are more than 30 years old and were not written to address modern hydraulic fracturing activities. In preparing this proposed rule, the BLM has received input from members of the public and stakeholders, and has initiated consultation with tribal representatives. The BLM is looking forward to obtaining additional public input and to ongoing tribal consultations regarding the specific proposed provisions that are set forth herein.

The BLM has analyzed the costs and the benefits of this proposed action in an accompanying Regulatory Impact Analysis available in the rulemaking docket. The estimated benefits range from $12 million to $50 million per year, with the range being based on the discount rate used for the analysis, and the estimates of the underlying risk reduced, and remediation costs avoided, by the regulation. The estimated costs range from $37 million to $44 million per year, and do not vary based on the uncertainty in the underlying risk reduced by the rule. Given the assumptions made about the costs of remediating contamination and the fact that certain benefits were not quantified, the BLM believes that the quantified range of estimated outcomes could underestimate actual net benefits.

I. Public Comment Procedures
II. Background
III. Discussion of the Proposed Rule
IV. Procedural Matters

I. Public Comment Procedures

If you wish to comment, you may submit your comments by any one of several methods: *Mail:* You may mail comments to U.S. Department of the Interior, Director (630), Bureau of Land Management, Mail Stop 2134LM, 1849 C Street NW., Washington, DC 20240, Attention: 1004–AE26. *Personal or messenger delivery:* Bureau of Land Management, 20 M Street SE., Room 2134 LM, Attention: Regulatory Affairs, Washington, DC 20003. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions at this Web site.

You may submit comments on the information collection burdens directly to the Office of Management and Budget, Office of Information and Regulatory Affairs, Desk Officer for the Department of the Interior, fax 202–395–5806, or *oira_docket@omb.eop.gov.* Please include ''Attention: OMB Control Number 1004–XXXX'' in your comments. If you submit comments on the information collection burdens, please provide the BLM with a copy of your comments, at one of the addresses shown above.

Please make your comments as specific as possible by confining them to issues directly related to the content of this proposed rule, and explain the basis for your comments. The comments and recommendations that will be most useful and likely to influence agency decisions are:

1. Those supported by quantitative information or studies; and
2. Those that include citations to, and analyses of, the applicable laws and regulations.

The BLM is not obligated to consider or include in the Administrative Record for the rule comments received after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

Comments, including names and street addresses of respondents, will be available for public review at the address listed under **ADDRESSES** during regular hours (7:45 a.m. to 4:15 p.m.), Monday through Friday, except holidays.

Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

II. Background

Well stimulation techniques, such as hydraulic fracturing, are used by oil and natural gas producers to increase the volumes of oil and natural gas that can be extracted from wells. Hydraulic fracturing techniques are particularly effective in enhancing oil and gas production from ''shale'' gas or oil formations. Until quite recently, shale formations rarely produced oil or gas in commercial quantities because shale does not generally generate flow of hydrocarbons to well bores unless mechanical changes to the properties of the rock can be induced. The development of horizontal drilling, combined with hydraulic fracturing, have made the production of oil and gas from shale possible. Hydraulic fracturing involves the injection of fluid under high pressure to create or enlarge fractures in the reservoir rocks. The fluid that is used in hydraulic fracturing is usually accompanied by proppants, such as particles of sand, that are carried into the newly fractured rock and help keep the fractures open once the pressure from the fracturing operation is released. The proppant-filled fractures become conduits for fluid migration from the reservoir rock to the wellbore and the fluid is subsequently brought to the surface. In

addition to the water and sand (which together typically make up 98 to 99 percent of the materials pumped into a well during a fracturing operation), chemical additives are also frequently used. These chemicals can serve many functions in hydraulic fracturing, including limiting the growth of bacteria and preventing corrosion of the well casing. The exact formulation of the chemicals used varies depending on the rock formations, the well, and the requirements of the operator.

The BLM estimates that about 90 percent (approximately 3,400 wells per year) of wells currently drilled on Federal and Indian lands are stimulated using hydraulic fracturing techniques. Over the past 10 years, there have been significant technological advances in horizontal drilling, which is frequently combined with hydraulic fracturing. This combination, together with the discovery that these techniques can release significant quantities of oil and gas from large shale deposits, has led to production from geologic formations in parts of the country that previously did not produce significant oil or gas. The resulting expansion of oil and gas drilling into new parts of the country as a result of the availability of new horizontal drilling technologies has significantly increased public awareness of hydraulic fracturing and the potential impacts that it may have on water quality and water consumption.

The BLM's existing hydraulic fracturing regulations are found at 43 CFR 3162.3–2. These regulations were established in 1982 and last revised in 1988, long before the latest hydraulic fracturing technologies became widely used. In response to public interest in hydraulic fracturing and in the BLM's regulation of hydraulic fracturing, in particular, the Department of the Interior (Department) held a forum on hydraulic fracturing on November 30, 2010 in Washington, DC, attended by the Secretary of the Interior and more than 130 interested parties. The BLM later hosted public forums in Bismarck, North Dakota on April 20, 2011; Little Rock, Arkansas on April 22, 2011; and Golden, Colorado on April 25, 2011, to collect broad input on the issues surrounding hydraulic fracturing. More than 600 members of the public attended the April forums. Some of the comments frequently heard during these forums included concerns about water quality, water consumption, and a desire for improved environmental safeguards for surface operations. Commenters also strongly encouraged the agency to require public disclosure of the chemicals used in hydraulic fracturing operations on Federal and Indian lands.

Around the time of the BLM's forums, at the President's direction, the Secretary of Energy's Advisory Board convened a Natural Gas Subcommittee (Subcommittee) to evaluate hydraulic fracturing issues. The Subcommittee met with industry, service providers, state and Federal regulators, academics, environmental groups, and many others stakeholders. Initial recommendations were issued by the Subcommittee on August 18, 2011. Among other things, the report recommended that more information be provided to the public, including disclosure of the chemicals used in fracturing fluids. The Subcommittee also recommended the adoption of progressive standards for wellbore construction and testing. The initial report was followed by a final report that was issued on November 18, 2011. The final report recommended, among other things, that operators engaging in hydraulic fracturing prepare cement bond logs and undertake pressure testing to ensure the integrity of all casings. These reports are available to the public from the Department of Energy's Web site at *http://www.shalegas.energy.gov*.

The BLM's proposed rule is consistent with the American Petroleum Institute's (API) guidelines for well construction and well integrity (see API Guidance Document HF 1, Hydraulic Fracturing Operations—Well Construction and Integrity Guidelines, First Edition, October 2009).

Based on the input provided from a broad array of sources, including the individuals who spoke at the BLM's public forums and the recommendations of the Subcommittee, the BLM is proposing to make critical improvements to its regulations for hydraulic fracturing. The proposed regulations would be applied to all wells administered by the BLM, including those on Federal, tribal, and individual Indian trust lands.

Tribal consultation is a critical part of this effort, and the Department is committed to making sure tribal leaders play a significant role as we work together to develop resources on public and Indian lands in a safe and responsible way. The BLM has initiated government-to-government consultation with tribes on this proposal and has offered to hold follow-up consultation meetings with any tribe that desires to have an individual meeting. The BLM held four tribal consultation meetings, to which over 175 tribal entities were invited. These initial consultations were held in Tulsa, Oklahoma on January 10, 2012; in Billings, Montana on January 12, 2012; in Salt Lake City, Utah on January 17, 2012; and in Farmington, New Mexico on January 19, 2012. Eighty-one tribal members representing 27 tribes attended the meetings. In these sessions, tribal representatives were given a discussion draft of the hydraulic fracturing rule to serve as a basis for substantive dialogue about the hydraulic fracturing rulemaking process. The BLM asked the tribal leaders for their views on how a hydraulic fracturing rule proposal might affect Indian activities, practices, or beliefs if it were to be applied to particular locations on Indian and public lands. A variety of issues were discussed, including applicability of tribal laws, validating water sources, inspection and enforcement, wellbore integrity, and water management, among others. Additional individual consultations with tribal representatives have taken place since that time. One of the outcomes of these meetings is the proposed requirement in this rule that operators certify that operations on tribal lands comply with tribal laws.

The BLM has been and will continue to be proactive about tribal consultation under the Department's newly-formalized Tribal Consultation Policy, which emphasizes trust, respect and shared responsibility in providing tribal governments an expanded role in informing Federal policy that impacts Indian lands. The BLM will continue to consult with tribal leaders throughout the rulemaking process. Responses from tribal representatives will inform the agency's actions in defining the scope of acceptable hydraulic fracturing rule options. Tribal governments, tribal members, and individual Native Americans are also invited to comment directly on this proposed rule through the process described in the Public Comment Procedures section of this document.

Over the past few years, in response to strong public interest, several states—including Colorado, Wyoming, Arkansas, and Texas—have substantially revised their state regulations related to hydraulic fracturing. One of the BLM's key goals in updating its regulations on hydraulic fracturing is to complement these state efforts by providing a consistent standard across all public and Indian lands. The BLM is also actively working to minimize any duplication between the reporting required for state regulations and for this regulation and to make reported information consistent and easily accessible to the public. For instance, the BLM is working closely with the Ground Water Protection Council and the Interstate Oil and Gas

Commission in an effort to integrate the disclosure called for in this rule with the existing Web site known as FracFocus. The FracFocus.org Web site is already well established and used by many states. This online database includes information from oil and gas wells in roughly 12 states and includes information from over 206 companies. The BLM understands that the database is in the process of being improved and will in the near future have enhanced search capabilities and allow for easier reporting of information.

The BLM recognizes the efforts of states to regulate hydraulic fracturing and is focused on coordinating closely with individual state governments to avoid duplicative regulatory requirements. The agency has a long history of working cooperatively with state regulators and the BLM often enters into memorandums of understanding or establishes working groups to coordinate state and Federal activities, such as the oil and gas working groups that currently exist in many of our oil and gas states. The BLM is applying the same approach to this effort and will work closely with individual states on the implementation of the proposed regulation. The BLM's intent is to encourage efficiency in the collection of data and the reporting of information. The BLM routinely shares information on oil and gas operations with state regulatory authorities and the BLM will continue to work with individual states to ensure that duplication of efforts is avoided to the extent possible. Since the BLM is looking for all opportunities to avoid duplication of the collection of data and the reporting of information, we are specifically asking for public comment on how best to avoid duplication of requirements under this proposed rule with existing state requirements.

The BLM acknowledges that some states already have in place rules and regulations that address hydraulic fracturing and that these rules may be either more or less stringent than the provisions in this proposal. In keeping with longstanding practice and consistent with relevant statutory authorities, it is the intention of the BLM to implement on public lands whichever rules, state or Federal, are most protective of Federal lands and resources and the environment.

III. Discussion of the Proposed Rule

The BLM proposes to revise its hydraulic fracturing regulations, found at 43 CFR 3162.3–2, and adding a new section 3162.3–3. Existing section 3162.3–3 would be retained and renumbered. The Federal Land Policy and Management Act (FLPMA) directs the BLM to manage the public lands so as to prevent unnecessary or undue degradation, and to manage lands using the principles of multiple use and sustained yield. FLPMA declares multiple use to mean, among other things, a combination of balanced and diverse resource uses that takes into account long-term needs of future generations for renewable and non-renewable resources. FLPMA also requires that the public lands be managed in a manner that will protect the quality of their resources, including ecological, environmental, and water resources. The Mineral Leasing Act and the Mineral Leasing Act for Acquired Lands authorize the Secretary to lease Federal oil and gas resources, and to regulate oil and gas operations on those leases, including surface-disturbing activities. The Indian Mineral Leasing Act assigns regulatory authority to the Secretary over Indian oil and gas leases on trust lands (except those excluded by statute). As stewards of the public lands, and as the Secretary's regulator for oil and gas leases on Indian lands, the BLM has evaluated the increased use of well stimulation practices over the last decade and determined that the existing rules for well stimulation require updating.

The current regulations make a distinction between routine fracture jobs and nonroutine fracture jobs. However, the terms ''routine'' and ''nonroutine'' are not defined in 43 CFR 3162.3–2 or anywhere else in BLM regulations, making this distinction functionally difficult to apply and confusing for both the agency and those attempting to comply with the regulations. As previously stated, the regulations are now 30 years old and need to be updated to keep pace with the many changes in technology and current best management practices. As discussed in the background section of this document, the increased use of well stimulation activities over the last decade has also generated concerns among the public about well stimulation and about the chemicals used in hydraulic fracturing. The proposed rule is intended to increase transparency for the public regarding the fluids used in the hydraulic fracturing process, in addition to providing assurances that well bore integrity is maintained throughout the fracturing process and that the fluids that flow back to the surface from hydraulic fracturing operations are properly stored and disposed of or treated.

The following chart explains the major changes between the existing regulation(s) and the proposed regulation(s).

Existing regulation	Proposed regulation	Substantive changes
43 CFR 3160.0–5 Onshore Oil and Gas Operations: General Definitions.	43 CFR 3160.0–5 Onshore Oil and Gas Operations: General Definitions.	This proposal would replace the current definition of usable water found in 43 CFR 3162.5–2(d) and define six other terms used in the oil and gas drilling industry to make the rule clearer and easier to understand. The definitions would be consistent with those used in the BLM's Oil and Gas Onshore Orders and by industry.
43 CFR 3162.3–2(a) Subsequent Well Operations.	43 CFR 3162.3–2(a) Subsequent Well Operations.	This proposal would remove the phrase ''performing nonroutine fracturing jobs.''
43 CFR 3162.3–2(b) Subsequent Well Operations.	43 CFR 3162.3–2(b) Subsequent Well Operations.	This proposal would remove the phrase ''routine fracturing or acidizing jobs, or * * *''
No existing regulation	43 CFR 3162.3–3(a) through (j)	This proposal would add provisions addressing well stimulation operations, would require disclosure of well stimulation fluids, and would require approval of well stimulation operations. The proposed rule would also require that mechanical integrity tests be conducted before well stimulation activities are conducted and would require full reporting of the results of the well stimulation activity within thirty days of its completion. This proposal would also add a section allowing the authorized officer to grant a variance to specific conditions of these rules if the operator can demonstrate that alternative procedures would meet or exceed the intent of the minimum standards in this rule. This variance language is consistent with that found in the BLM's Oil and Gas Onshore Orders.

Existing regulation	Proposed regulation	Substantive changes
43 CFR 3162.5–2(d) Protection of fresh water and other minerals.	43 CFR 3162.5–2(d) Protection of fresh water and other minerals.	This proposal removes the definition of usable water from this section. The new definition of usable water would be placed in 43 CFR 3160.0–5.

Section-by-Section Discussion of Proposed Changes

As an administrative matter, the proposed rule would amend the authorities section for the BLM's oil and gas operations management regulations at 43 CFR 3160.0–3 to include FLPMA. Section 310 of FLPMA authorizes the Secretary of the Interior to promulgate regulations to carry out the purposes of FLPMA and other laws applicable to the public lands. See 43 U.S.C. 1740. This amendment would not be a major change and would have no effect on lessees, operators, or the public.

The proposed rule would remove the terms ''nonroutine fracturing jobs,'' ''routine fracturing jobs,'' and ''acidizing jobs'' from 43 CFR 3162.3–2(a) and 43 CFR 3162.3–2(b). It would add a new section, 43 CFR 3162.3–3, for well stimulation activities. In the proposed rule, there would be no distinction drawn between what was previously considered nonroutine or routine well stimulations. Prior approval would be required for well stimulation activities, generally in connection with the prior approval process that already is in place for general well drilling activities through the Application for Permit to Drill (APD) process. Operators also will be required to submit cement bond logs before fracturing operations begin. The running of cement bond logs on surface casing, which is currently an optional practice, would now be required for new wells. Existing wells would require mechanical integrity testing prior to hydraulic fracturing.

The proposed rule would include six new definitions for technical terms used in the proposed rule. These definitions will improve readability and clarity of the regulations.

The proposed rule intends to add the following definitions:

- *Annulus* means the space around a pipe in a wellbore, the outer wall of which may be the wall of either the borehole or the casing; sometimes also called the *annular space.*
- *Bradenhead* means a heavy, flanged steel fitting connected to the first string of casing that allows suspension of intermediate and production strings of casing, and supplies the means for the annulus to be sealed off.
- *Proppant* means a granular substance (most commonly sand, sintered bauxite, or ceramic) that is carried in suspension by the fracturing fluid and that serves to keep the cracks open when fracturing fluid is withdrawn after a hydraulic fracture treatment.
- *Stimulation fluid* means the liquid or gas, and any accompanying solids, used during a treatment of oil and gas wells, such as the water, chemicals, and proppants used in hydraulic fracturing.
- *Usable water* means water containing up to 10,000 ppm of total dissolved solids.
- *Well stimulation* means those activities conducted in an individual well bore designed to increase the flow of hydrocarbons from the rock formation to the well bore by modifying the permeability of the reservoir rock. Examples of well stimulation operations are acidizing and hydraulic fracturing.

The proposed rule would delete the definition of ''fresh water.'' The BLM has maintained a definition of fresh water in its oil and gas operating regulations since 1988. However, in its onshore orders, the BLM has sought to protect all usable waters during drilling operations, not just fresh water. This distinction has led to confusion in the regulations. Usable water includes fresh water and water that is of lower quality than fresh water. The BLM intends to be more protective when it seeks to protect all usable water during drilling operations, not just fresh water. Therefore, the BLM proposes to delete the definition of fresh water.

Revised section 3162.3–2(a) would remove the phrase ''perform nonroutine fracturing jobs'' from the current 43 CFR 3162.3–2(a). The phrase ''routine fracturing jobs or acidizing jobs, or'' would also be removed from existing section 3162.3–2(b). Well stimulation activities would be addressed under the new proposed 43 CFR 3162.3–3.

Proposed section 3162.3–3(a) would make it clear that this section applies only to well stimulation activities and that all other injection activities must comply with section 3162.3–2. This language is necessary to make the distinction between well stimulation activities and other well injection activities, such as secondary and tertiary recovery operations.

Proposed section 3162.3–3(b) would require the BLM's approval of all well stimulation activity. For new wells, the operator has the option of applying for the BLM's approval in its application for permit to drill (APD). For wells permitted prior to the effective date of this section or for wells permitted after the effective date of this section, the operator would submit a Sundry Notice and Report on Wells (Form 3160–5) for the well stimulation proposal for the BLM's approval before the operator begins the stimulation activity. This section would supersede and replace existing section 3162.3–2(b) that states that no prior approval is required for routine fracturing. This reference in the existing section would be deleted. Also, an operator must submit a Sundry Notice prior to well stimulation activity if the BLM's previous approval for well stimulation is more than five years old, or if the operator becomes aware of significant new information about the relevant geology, the stimulation operation or technology, or the anticipated impacts to any resource. The five-year period is consistent with common state practices, including those of Montana, Wyoming, and Colorado, which require that operators reconfirm well integrity for fracturing operations through a pressure test every five years.

The BLM understands the time sensitive nature of oil and gas drilling and well completion activities and does not anticipate that the submittal of additional well stimulation-related information with APD applications will impact the timing of the approval of drilling permits. The BLM believes that the additional incremental information that would be required by this rule would be reviewed in conjunction with the APD and within the normal APD processing time frame. Also, the BLM anticipates that requests to conduct well stimulation activities on existing wells that have been in service more than five years will be reviewed promptly. The BLM understands that delays in approvals of operations can be costly to operators and the BLM intends to avoid delays whenever possible.

Proposed section 3162.3–3(c)(1) would require a report that includes the geological names, a geological description, and the depth of the top and the bottom of the formation into which well stimulation fluids would be injected. The report is needed so that the BLM may determine the properties of the rock layers and the thickness of the producing formation and identify

the confining rocks above and below the zone that would be stimulated.

Proposed section 3162.3–3(c)(2) would require the operator to submit information in the form of a cement bond log, which will help the BLM in its efforts to make sure that water resources are protected. A cement bond log is a tool used to gauge the extent to which water bearing formations are isolated from the casing string. The log is a document that reports the data from a probe of the wellbore that uses sonic technology to detect gaps or voids in the cement and the casing. This log would be used to verify that the operator has taken the necessary precautions to prevent migration of fluids in the annulus from the fracture zone to the usable water horizons. The proposed regulation would allow for the use of other evaluation tools acceptable to the BLM in order to allow the substitution of equally effective tools or procedures. For example, an operator could request a variance from the requirements of proposed section 3162.3–3(c)(2) that it submit cement bond logs to prove that the occurrences of usable water have been isolated to protect them from contamination. The BLM could grant a variance to allow for the use of logs other than cement bond logs (e.g., slim array sonic tool, ultrasonic imager tool) if it was satisfied that the alternative logs would meet or exceed the objectives of section (c)(2). The BLM recognizes that the cement bond log would not be available prior to drilling a well. Therefore, when the operator takes advantage of the option to submit its well stimulation information as part of its APD, the cement bond log would be required after approval of the permit to drill and prior to commencing well stimulation activities. Many operators routinely perform cement bond logs for the zones of interest, so the BLM does not expect this step to be a burden for operators. The best available means for the BLM to help ensure that well stimulation activities do not contaminate aquifers is to require cement bond logs for the cement behind the pipe along all areas intersecting useable water, including running cement bond logs on the surface casing.

Proposed section 3162.3–3(c)(3) would require reporting of the measured depth to the perforations in the casing and uncased hole intervals (open hole). This proposed section would also require the operator to disclose specific information about the water source to be used in the fracturing operation, including the location of the water that would be used as the base fluid. The BLM needs this information to determine the impacts associated with operations and the need for any mitigation applicable to Federal and Indian lands. This section would also require the operator to disclose the type of materials (proppants) that would be injected into the fractures to keep them open and the anticipated pressures to be used in the well stimulation operation.

Proposed section 3162.3–3(c)(4), consistent with protecting public health and safety and preventing unnecessary or undue degradation to the public lands, would require operators to certify in writing that they have complied with all applicable Federal, tribal, state, and local laws, rules, and regulations pertaining to proposed stimulation fluids. The BLM will use this information to make an informed decision on the proposed action. This section also would require the operator to certify that it has complied with all necessary permit and notice requirements. The BLM acknowledges that other Federal, state, tribal, and local agencies may have regulatory requirements that would apply to chemical handling, injecting fluids into the subsurface, and the protection of groundwater. It remains the responsibility of the operator to be aware of and comply with these regulatory requirements. The BLM will rely on the operator's certification that it has complied with all of the laws and regulations that apply to its operation.

Proposed section 3162.3–3(c)(5) would require the operator to submit a detailed description of the well stimulation engineering design to the BLM for approval. This information is needed in order for the BLM to be able to verify that the proposed engineering design is adequate for safely conducting the proposed well stimulation.

Proposed section 3162.3–3(c)(5)(i) would require the operator to submit to the BLM an estimate of the total volume of fluid to be used in the stimulation.

Proposed section 3162.3–3(c)(5)(ii) would require the operator to submit to the BLM a description of the range of the surface treating pressures anticipated for the stimulation. This information is needed by the BLM to verify that the maximum wellbore design burst pressure will not be exceeded at any stage of the well stimulation operation.

Proposed section 3162.3–3(c)(5)(iii) would require the operator to submit to the BLM the proposed maximum anticipated injection pressure for the stimulation. This information is needed by the BLM to verify that the maximum allowable injection pressure will not be exceeded at any stage of the well stimulation operation.

Proposed section 3162.3–3(c)(5)(iv) would require the operator to submit to the BLM the estimated or calculated fracture length and height anticipated as a result of the stimulation, so that the BLM can verify that the intended effects of the well stimulation operation will remain confined to the petroleum-bearing rock layers and will not have unintended consequences on other rock layers, such as aquifers.

Proposed section 3162.3–3(c)(6) would require the operator to provide information pertaining to the handling of recovered fluids that will be used for the stimulation activities for approval. This information is being requested so that the BLM has all necessary information regarding chemicals being used in the event that the information is needed to help protect health and safety or to prevent unnecessary or undue degradation of the public lands.

Proposed section 3162.3–3(c)(6)(i) would require the operator to submit to the BLM an estimate of the volume of fluid to be recovered during flow back, swabbing, and recovery from production facility vessels. This information is required to ensure that the facilities needed to process or contain the estimated volume of fluid will be available on location.

Proposed section 3162.3–3(c)(6)(ii) would require the operator to submit to the BLM the proposed methods of managing the recovered fluids. This information is needed to ensure that the handling methods will adequately protect of public health and safety.

Proposed section 3162.3–3(c)(6)(iii) would require the operator to submit to the BLM a description of the proposed disposal method of the recovered fluids. This is currently required by existing BLM regulations (i.e., Onshore Order Number 7, Disposal of Produced Water, (58 FR 47354). This information is requested so that the BLM has all necessary information regarding disposal of chemicals used in the event it is needed to protect the environment and human health and safety and to prevent unnecessary or undue degradation of the public lands. The BLM specifically requests comments on whether the operator should be required to submit as part of the Sundry Notice application additional information about how it will dispose of waste streams not specifically addressed in this proposal.

Proposed section 3162.3–3(c)(7) would require the operator to provide, at the request of the BLM, additional information pertaining to any facet of the well stimulation proposal. For example, the BLM may require new or different tests or logs in cases where the

original information submitted was inadequate, out of date, or incomplete. Any new information that the BLM may request will be limited to information necessary for the BLM to ensure that operations are consistent with applicable laws and regulation. Such information may include, but is not limited to, tabular or graphical results of a mechanical integrity test, the results of logs run, the results of tests showing the total dissolved solids in water proposed to be used as the base fluid, and the name of the contractor performing the stimulation. This provision would allow the BLM to obtain additional information about the proposed well stimulation activities. For example, after initial cementing activities, an operator may be asked to perforate the well casing and squeeze cement into the areas with inadequate cement bonding. In this case, the BLM may ask for additional information to show that the corrective action was successful and to ensure that the corrective work addressed any cement bonding deficiencies. The BLM wants to ensure that any additional information requested under this provision is the least burdensome to operators as possible while still accomplishing the goal of protecting the public lands and resources; therefore, the BLM is specifically requesting public comment on how this may be best achieved.

Proposed section 3162.3–3(d) would require the operator to perform a successful mechanical integrity test before beginning well stimulation operations. This requirement is necessary to help ensure the integrity of the wellbore under anticipated maximum pressures during well stimulation operations.

Proposed section 3162.3–3(d)(1) would require the mechanical integrity test to emulate the pressure conditions that would be seen in the proposed stimulation process. This test would show that the casing is strong enough to protect water and other subsurface resources during well stimulation activities.

The proposed section 3162.3–3(d)(2) would establish the engineering criteria for using a fracturing string as a technique during well stimulation. The requirement to be 100 feet below the cement top would be imposed to ensure that the production or intermediate casing is surrounded by a competent cement sheath as required by Onshore Order Number 2. The 100 foot requirement is required by some state statutes (e.g., Montana Board of Oil and Gas Conservation, section 36.22.1106, Hydraulic Fracturing) and is a generally accepted standard in the industry. Testing would emulate the pressure conditions that would be seen in the proposed stimulation process in order to ensure that the casing used in the well would be robust enough to handle the pressures.

Proposed section 3162.3–3(d)(3) would require the use of the pressure test time requirement of holding pressure for 30 minutes with no more than 10 percent pressure loss. This requirement is the same standard applied in Onshore Order Number 2, Drilling, (53 FR 46790) Section III.B.h., to confirm the mechanical integrity of the casing. This language does not set a new standard in the BLM's regulations. This test, together with the other proposed requirements, would demonstrate if the casing is strong enough to protect water and other subsurface resources during well stimulation activities. The BLM believes that all of these tests are important to show that reasonable precautions have been taken to ensure the protection of other resources during well stimulation activities.

Proposed section 3162.3–3(e)(1) would require the operator to continuously monitor and record the pressure(s) during the well stimulation operation. The pressure during the stimulation should be contained in the string through which the stimulation is being pumped. Unexpected changes in the monitored and recorded pressure(s) would provide an early indication of the possibility that well integrity has been compromised. This information is needed by the BLM to ensure that well stimulation activities are conducted as designed. This information would also show that stimulation fluids are going to the formation for which they were intended.

Proposed section 3162.3–3(e)(2) would require the operator to orally notify the BLM as soon as possible, but no later than 24 hours following the incident, if during the stimulation operation the annulus pressure increases by more than 500 pounds per square inch over the annulus pressure immediately preceding the stimulation. Within 15 days after the occurrence, the operator must submit a Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Report on Wells) to the BLM containing all details pertaining to the incident, including corrective actions taken. This information is needed by the BLM to ensure that stimulation fluids are going into the formation for which they were designed. The BLM also needs to obtain reasonable assurance that other resources are adequately protected. An increase of pressure in the annulus of this amount could indicate that the casing had been breached during well stimulation. Consistent with the BLM's Onshore Order Number 2, Drilling Operations, the operator must repair the casing should a breach occur.

Proposed section 3162.3–3(f) would require the operator to store recovered fluids in tanks or lined pits. This provision grants flexibility for the operator to choose using either a lined pit or a storage tank, whichever the operator determines is the least burdensome or costly option for the storage of flowback fluid. The BLM is proposing this requirement because flowback fluids could contain hydrocarbons from the formation and could also contain additives and other components that might degrade surface and ground water if they were to be released without treatment. This provision is consistent with existing industry practice and American Petroleum Institute (API) recommendations for handling completion fluids (including hydraulic fracturing fluids) (see Section 6.1.6 of API Recommended Practice 51R, Environmental Protection for Onshore Oil and Gas Production Operations and Leases, First Edition, July 2009). Section 302(b) of the Federal Land Policy and Management Act (43 U.S.C. 1732(b)) states that ''In managing the public lands, the Secretary shall, by regulation or otherwise, take any action necessary to prevent unnecessary or undue degradation of the public lands.'' In addition, existing BLM regulations at 43 CFR 3161.2 requires that ''all operations be conducted in a manner which protects other natural resources and the environmental quality.'' Because the use of lined pits or tanks for the storage of recovered fluids are methods that best and reasonably protect the public lands from spills or leaks of recovered fluids, the BLM believes that this provision is in keeping with FLPMA's mandate to prevent unnecessary or undue degradation of the public lands and the BLM regulation's requirement to protect environmental quality.

Additional conditions of approval for the handling of flowback water may be placed on the project by the BLM if needed to ensure protection of the environment and other resources. The BLM specifically requests comments on whether this rule should impose additional requirements that would require tanks or lined pits for drilling fluids and any other fluids associated with well stimulation operations. The BLM recognizes the ongoing efforts of states to regulate hydraulic fracturing operations. In implementing this rule, the BLM intends to avoid duplication of

existing state requirements and will continue to engage states in cooperative efforts to avoid duplication. Please comment on whether this proposed provision would be duplicative of provisions of state rules and whether it is unnecessarily burdensome.

Proposed section 3162.3–3(g) would require the operator to submit to the BLM the post-operation data on a Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Report on Wells) following the completion of the stimulation activities. The BLM would determine if the well stimulation operation was conducted as approved. This information would be retained by the BLM as part of the individual well record and would be available for use when the well has been depleted and the plugging of the well is being designed.

Proposed section 3162.3–3(g)(1) would require reporting of the actual measured depth to the perforations and open hole interval. This information identifies the producing interval of the well and will be available for use when the well has been depleted and plugging of the well is being designed. Specific information as to the actual source of water, including location of the water being used as the base fluid, is required because the BLM needs the information to determine the impacts associated with operations and the need for any mitigation applicable to Federal and Indian lands.

Proposed section 3162.3–3(g)(2) would require the operator to submit to the BLM the actual total volume of fluid used, including water, proppants, chemicals, and any other fluid used in the stimulation(s) in order for the BLM to maintain a record of the stimulation operation as actually performed.

Proposed section 3162.3–3(g)(3) would require the operator to submit to the BLM a report of the surface pressure at the end of each stage pumped and the rate at which the fluid was pumped at the completion of each stage (i.e., just prior to shutting down the pumps). In addition to the information provided for the individual stages, the pressure values for each flush stage must also be included. This information is needed by the BLM for it to ensure that the maximum allowable pressure was not exceeded at any stage of the well stimulation operation.

Proposed sections 3162.3–3(g)(4) and (5) would require the operator to identify to the BLM the stimulation fluid by additive trade name and additive purpose, the Chemical Abstracts Service Registry Number, and the percent mass of each ingredient used in the stimulation operation. This information is needed in order for the BLM to maintain a record of the stimulation operation as performed. The information is being required in a format that does not link additives (required by 3162.3–3(g)(4)) to chemical composition of the materials (required by 3162.3–3(g)(5)) to minimize the risk of disclosure of any formulas of additives. This approach is similar to the one the State of Colorado adopted in 2011 (Colorado Oil and Gas Conservation Commission Rule 205A.b2.ix–xii). The BLM intends to place this information on a public Web site and is working with the Ground Water Protection Council in an effort to integrate this information into the existing Web site known as FracFocus.org. The disclosure of the fluids used in hydraulic fracturing would only be required after the fracturing operation has taken place.

Proposed section 3162.3–3(g)(6) would require the actual, estimated, or calculated fracture length and height of the stimulation(s) to be reported to the BLM so that it can verify that the intended effects of the well stimulation operation remain confined to the petroleum-bearing rock layers and will not have unintended consequences on other rock layers or aquifers. This section would require the operator to show that the well stimulation activity was successfully implemented as designed and that the integrity of the well was maintained during stimulation.

Proposed section 3162.3–3(g)(7) would allow the operator flexibility to report online the information listed in proposed sections 3162.3–3(g)(1) through 3162.3–3(g)(6) by attaching a copy of the service company contractor's job log or report, provided the information required is adequately addressed. The operator is responsible for ensuring the accuracy of any information provided to the BLM, even if originally drafted by a third party.

Proposed section 3162.3–3(g)(8), would require operators to certify they have complied with all applicable Federal, state, tribal, and local laws, rules, and regulations pertaining to the stimulation fluids that were actually used during well stimulation operations. The proposed section would also require that the operator certify that it has complied with all necessary permit and notice requirements. This information would be retained by the BLM as part of the well record and be available for use when the well has been depleted and closure of the well is being designed. The information is also needed for the BLM to fulfill its obligation to prevent unnecessary or undue degradation of the public land.

Proposed section 3162.3–3(g)(9) would require operators to certify that wellbore integrity was maintained throughout the operation. This information is needed because the BLM has a mandate to protect human health and safety and prevent contamination of the environment.

Proposed section 3162.3–3(g)(10) would require the operator to provide information describing the handling of the fluids used for the stimulation activities, flow-back fluids, and produced water. The operator must also report how it handled those fluids after operations were completed.

Proposed section 3162.3–3(g)(10)(i) would require the operator to report the volume of fluid recovered during flow back, swabbing, or recovery from production facility vessels.

Proposed section 3162.3–3(g)(10)(ii) would require the operator to report the methods of managing the recovered fluids.

Proposed section 3162.3–3(g)(10)(iii) would require the operator to report the disposal method of the recovered fluids. This section also makes it clear that the fluid disposal methods must be consistent with Onshore Order Number 7, Disposal of Produced Water (58 FR 47353). This information is needed so that the BLM can help protect human health and safety and prevent the contamination of the environment. The BLM also needs to confirm that the disposal methods used are those that were approved and conform to the regulations.

Proposed section 3162.3–3(g)(11) would require the operator to submit documentation and an explanation if the actual operations deviated from the approved plan. Understanding the complexities of well stimulation, the BLM expects there to be slight differences between the proposed plan and the actual operation.

Proposed sections 3162.3–3(h) and (i) would notify the operator of procedures it needs to follow to identify information required to be submitted under this section that the operator believes to be exempt, by law, from public disclosure. If the operator fails to specifically identify information as exempt from disclosure by Federal law, the BLM will release that information. The BLM may also release information which the operator has marked as exempt if the BLM determines that public release is not prohibited by Federal law after providing the operator with no fewer than 10 business days' notice of the determination. All other

information submitted by the operator will become a matter of public record.

Proposed section 3162.3–3(j) would provide the operator with a process for requesting a variance from the minimum standards of this regulation. Variances apply only to operational activities and do not apply to the actual approval process. The proposed regulation would make clear that the BLM has the right to rescind a variance or modify any condition of approval due to changes in Federal law, technology, regulation, field operations, noncompliance, or other reasons. The BLM must make a determination that the variance request meets or exceeds the objectives of the regulation. For example, an operator could request a variance from the requirements of proposed section 3162.3–3(c)(2) that it submit cement bond logs to prove that the occurrences of usable water have been isolated to protect them from contamination. The BLM could grant a variance to allow for the use of logs other than cement bond logs if it was satisfied that the alternative logs would meet or exceed the objectives of section (c)(2). This variance provision is consistent with existing BLM regulation such as Onshore Order Number 1 (see section X. of Onshore Oil and Gas Operations; Federal and Indian Oil and Gas Leases; Onshore Oil and Gas Order Number 1, Approval of Operations (72 FR 10308, 10337).

Revised section 3162.5–2(d) would remove the references to fresh water and remove the phrase ''containing 5,000 ppm or less of dissolved solids.'' This revision would require the operator to isolate all usable water. This language does not set a new standard in the BLM's regulations. Since 1988, Onshore Order Number 2, Drilling Operations, (53 FR 46790) Section II.Y. has defined usable water and Onshore Order Number 2, Drilling Operations, Section III.B. has required the operator to ''protect and/or isolate all usable water zones.'' Section 3162.5(d) was not revised when Onshore Order Number 2, Drilling Operations, was promulgated, which has led to some confusion in implementing and interpreting the regulations.

IV. Procedural Matters

Federal and Indian Oil and Gas Leasing Activity

To understand the context of costs and benefits of the proposed rule, background information concerning the BLM's leasing of Federal oil and gas, and management of Federal and Indian leases may be helpful and is included here. This discussion is provided to explain the basis for the conclusions related to the procedural matters sections that follow. The BLM Oil and Gas Management program is one of the most important mineral leasing programs in the Federal Government. There were 49,173 Federal oil and gas leases covering 38,463,410 acres at the end of fiscal year (FY) 2011. For FY 2011, there were 90,452 producible and service drill holes and 96,606 producible and service completions on Federal leases.[1]

For FY 2011, onshore Federal oil and gas leases produced about 98 million barrels of oil, 2.97 billion Mcf of natural gas, 2.55 billion gallons of natural gas liquids, and approximately $2.7 billion in royalties. The production value of the oil and gas produced from public lands exceeded $23 billion. Oil and gas production from Indian leases was almost 20 million barrels of oil, 255 million Mcf of natural gas, and 143 million gallons of natural gas liquids, with a production value of $2.7 billion and generating royalties of $433 million.

TABLE 1—FEDERAL AND INDIAN OIL AND GAS PRODUCTION AND ROYALTIES, FISCAL YEAR 2011

	Sales volume	Sales value ($MM)	Royalty ($MM)
Federal Leases:			
Oil (bbl)	97,721,813	$8,374	$1,111
Gas (Mcf)	2,974,916,041	12,556	1,360
NGL (Gal)	2,551,994,725	2,474	254
Subtotal		23,404	2,725
Indian Leases:			
Oil (bbl)	19,550,536	1,571	271
Gas (Mcf)	255,401,453	950	145

Source: ONRR, Federal Onshore Reported Royalty Revenue, Fiscal Year 2011 and American Indian Reported Royalty Revenue, Fiscal Year 2011.

Estimating Benefits and Costs

This analysis attempts to capture the potential benefits and costs that would result if the BLM implemented the proposed rule. As such, the current operating environment is the reference point from which the change is measured.

Current regulations require operators conducting a ''non-routine'' well stimulation operation to submit a Notice of Intent Sundry and all operators, regardless of the type of well stimulation, to submit a Subsequent Report Sundry. The proposed rule would require BLM approval for all hydraulic fracturing events. For each event, operators would obtain the BLM's approval prior to the event and submit a Subsequent Report Sundry within 30 days of the event. The operator, if it so chooses, may seek approval for the stimulation operation at the same time that it submits the APD. Other information would be required if an incident occurs during a fracturing operation or if the BLM determines that there is a need for additional information. For example, the BLM may require new or different information in cases where the original information submitted in the Subsequent Report was inadequate or incomplete.

Potential costs and benefits rely on the number of well stimulation events estimated to occur in the future. Those estimates depend on a number of factors, including, but not limited to, future oil and gas prices, the number of applications to drill, the number of wells completed, and the portion of wells that are stimulated. Expected costs and benefits are anticipated to increase in the future because the number of wells drilled and well stimulation activities are expected to increase in the

[1] U.S. Department of the Interior, Bureau of Land Management, *www.blm.gov*, Oil and Gas Statistics.

future, considering projected commodities prices and production.

Administrative costs include only the additional burden posed by the requirements. For operators, this burden includes the submission of forms and supporting documentation that are not currently required. The reporting requirements would also pose an additional burden on the BLM, since it would review an additional number of sundry forms and additional information per form. The efficiency of processing applications could also be impacted if operators submit incomplete or inadequate information, thereby requiring additional communication between the BLM and the operators.

The proposed rule seeks to achieve benefits by making more information available to the public about the chemicals injected in well stimulation fluids, while protecting trade secrets and confidential business information. The information that would be submitted to the BLM under this section would generally be made available to the public. The proposed rule, however, would allow an operator to identify specific information that it believes is protected from disclosure by Federal law, and to substantiate those claims of exemption. Under existing law, the BLM may nonetheless make that information available to the public, but only if it determines that the information is not protected by Federal law, and provides not less than 10 business days notice to the operator before releasing the information.

Furthermore, the disclosure mechanism in the proposed rule would require a table of the additives by trade name and the purpose for which they are included in the well stimulation fluid. It would also require a separate table listing all the chemicals used by the Chemical Abstracts Service Registry Number. This design will inhibit reverse-engineering of specific additives.

Potential costs include those to perform tests or take other actions that might not have been conducted otherwise. Operational costs include the cost of any additional logs, tests, or other requirements needed to prepare all documents required by the proposed rule that are not currently required. Depending on the well and the operator, these tests or other requirements currently may be conducted or practiced pursuant to other permits, general well testing, etc.

New wells, where operators are conducting hydraulic fracturing operations, should already comply with many of the standards provided in this proposed rule, with the exception of running cement bond logs on the surface casing. Typically, an operator will assume that the casing is fully cemented if cement circulates to the surface during the cementing process. However, circulation to the surface does not confirm that there is appropriate or proper bonding. A cement bond log will provide confirmation that there is proper bonding by providing a graphical representation that proper bonding has occurred. Old vertical wells that are converted to horizontal wells already require a deepening sundry, a separate process that addresses some of the requirements in this proposed rule.

The potential benefits of the proposed regulations include reduced surface and subsurface contamination. The analysis assumes that, absent this regulation, a certain number of well stimulation events may result in contamination and pose a cost to society. The proposed rule is designed to identify potential issues regarding wellbore integrity and the design of the operations, thereby reducing the likelihood of contamination events.

Estimating the benefits of the proposed regulation is uncertain and subject to assumptions about the number of deficiencies, likelihood of contamination if a deficiency was present, and costs of remediation. One way to measure this benefit is by estimating the cost of internalizing the contamination, which for a subsurface event may include restoring a source of drinking water or remediation of an aquifer.

There are other benefits that are difficult to quantify in monetary terms though they exist. The disclosure requirements might encourage operators to use fewer or safer chemicals in the hydraulic fracturing fluid. The public would benefit from increased knowledge about the fluids used. Increased transparency is also likely to benefit scientists, state and Federal agencies, and other organizations that study the potential impacts of hydraulic fracturing operations, and the BLM would have more information with which to make resource management decisions or respond to incidents.

Methodology

This analysis presents costs and benefits expected to occur over the next 10 years, from 2013 to 2022. This period of analysis was chosen because 10 years is the length of the primary lease term on BLM-managed lands. Net benefits are discounted using 7 and 3 percent discount rates. The analysis presents a range of expected outcomes since the number of well stimulation events occurring in the future is highly variable and subject to future conditions.

The proposed regulation is designed to reduce the risk that well stimulation events may pose to the environment. Any contamination event that occurs is expected to require remediation. Since the remediation costs are uncertain, the analysis makes assumptions about remediation costs which may underestimate the true costs of remediation. The analysis assumes two scenarios: A low remediation cost—low environmental risk scenario and a high remediation cost—high environmental risk scenario. The benefits, while representing the value of risk reduction, will underestimate or overestimate the true benefits if the true risk of well stimulation operations varies from the assumptions.

Discounted Present Value

There is a time dimension to estimates of potential benefits and costs. The potential events described, if they occur at all, may be in the distant future. The further in the future the benefits and costs are expected to occur, the smaller the present value associated with the stream of costs and benefits. As such, future costs and benefits must be discounted (the discount factor equals $1/(1+r)^t$ where r is the discount rate and t is time measured in years during which benefits and costs are expected to occur). The discount factor is then used to convert the stream of costs and benefits into ''present discounted values.'' When the estimated benefits and costs have been discounted, they can be added to determine the overall value of net benefits.

The OMB's basic guidance on the appropriate discount rate to use is provided in OMB Circular A–94. The OMB's Circular A–94 states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The OMB considers the 7 percent rate as an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. OMB Circular A–4 also states that a 3 percent discount rate should be used for regulatory analyses and explains the use of that discount rate as follows: ''The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private

consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the 'social rate of time preference.' This simply means the rate at which ''society'' discounts future consumption flows to their present value.''

Uncertainty

The benefits and costs provided in this analysis are indeed estimates and come with uncertainty. Estimated costs and benefits rely on the number of well stimulation events occurring in future years and those estimates are uncertain. This analysis estimates the number of future well stimulation events using regression models and future projections of commodity prices.

Assuming the number of well stimulation events is known, though administrative costs are more easily estimated, the operational costs required by producers to comply with the regulations are subject to assumptions about the number of wells that would require such expenditures.

Further uncertainty lies in the estimation of benefits and remediation costs. For the purposes of this analysis, a range of assumed average costs of remediating both subsurface and surface contaminations are used. This assumption may be too low or too high in the real world, depending on the location, severity, consequences, duration of the contamination, and if a causal link between the source and contamination can be made.

This analysis does not quantify other benefits that are undoubtedly relevant, such as the benefit that disclosing the components of fracturing fluids will have for public health research and the remediation of contamination events. It is also uncertain what additional benefits, if any, would result from the disclosure requirements, for instance, if companies find safer substitutes for the chemicals in the fracturing fluids.

Results

The analysis estimates the effects of the proposed regulations over a baseline scenario, where no action is taken. The BLM considered an alternative to the proposed regulation which would remove the requirement for operators to use lined pits if they choose to use pits to store hydraulic fracturing fluids.

A summary of the results appears in Table 2 and Table 3, with the entire results available in the full Economic Analysis and Initial Regulatory Flexibility Analysis available at the address listed in the **ADDRESSES** section of this rule.

TABLE 2—ANNUALIZED VALUE OF NET BENEFITS OF THE PROPOSED REGULATIONS AND ALTERNATIVES

[7% Discount rate; $MM]

	Low remediation cost/low environmental risk		High remediation cost/high environmental risk	
Proposed Regulations				
Social Benefits	11.70	13.79	42.67	50.27
Costs	37.34	43.99	37.34	43.99
Net Benefits	−25.63	−30.20	5.33	6.28
Alternative 1: No Requirement for Lined Pits				
Social Benefits	0.01	0.02	7.60	8.95
Costs	34.68	40.86	34.68	40.86
Net Benefits	−34.67	−40.84	−27.08	−31.90
Estimated Number of Well Stimulations	Low	High	Low	High
Total	31,328	37,015	31,328	37,015
Annual Average	3,133	3,701	3,133	3,701

TABLE 3—ANNUALIZED VALUE OF NET BENEFITS OF THE PROPOSED REGULATIONS AND ALTERNATIVES

[3% Discount rate; $MM]

	Low remediation cost/low environmental risk		High remediation cost/high environmental risk	
Proposed Regulations:				
Social Benefits	11.74	13.85	42.79	50.27
Costs	37.44	44.18	37.44	44.18
Net Benefits	−25.70	−30.33	5.35	6.31
Alternative 1: No Requirement for Lined Pits:				
Social Benefits	0.01	0.02	7.62	8.99
Costs	34.77	41.04	34.77	41.04
Net Benefits	−34.76	−41.02	−27.15	−32.04
Estimated Number of Well Stimulations	Low	High	Low	High
Total	31,328	37,015	31,328	37,015
Annual Average	3,133	3,701	3,133	3,701

Results for the Proposed Regulations (Preferred Approach)

Benefits: Under the proposed regulations, it is assumed that the regulations would remove much of the risk associated with potential wellbore integrity issues and unlined pits. The change in social benefits from the baseline scenario is positive. If you assume that there is low environmental risk posed by wellbore integrity issues and storage of hydraulic fracturing fluids in unlined pits and the costs of surface and subsurface remediation is low (on the range assumed), then the change in social benefit as a result of the proposed regulation is positive and ranges between $11.70MM and $13.79MM per year using a discount rate of 7% and between $11.74MM and $13.85MM per year using a discount rate of 3%. If you assume that environmental risks are high and remediation costs are high (on the range assumed), then the social benefits of the proposed regulation is positive and ranges between $42.67MM and $50.27MM per year using a discount rate of 7% and between $42.79MM and $50.49MM per year using a discount rate of 3%. Tables 7 and 8 (below) show the annual change in benefits over the baseline.

Note that the figures for the estimated benefits of the proposed rule do not include such benefits as avoiding harm to water users that cannot be compensated by later providing alternative water sources. The increase in information about additives could aid water users when they consider the potential effects of well stimulation operations and constituent chemicals.

Costs: The costs include both costs to the industry and the BLM under this alternative. Costs include operational tests that demonstrate wellbore integrity and those associated with lining open pits in the instances where operators use pits instead of storage tanks. The change in costs over the baseline ranges between $37.34MM and $43.99MM per year using a discount rate of 7% and between $37.44MM and $44.18MM per year using a discount rate of 3%, assuming low remediation costs and low environmental risks. The change in costs ranges between $37.34MM and $43.99MM per year using a discount rate of 7% and between $37.44MM and $44.18MM per year using a discount rate of 3%, assuming high remediation costs and high environmental risks. Tables 7 and 8 (below) show the annual change in costs over the baseline.

Net Benefits: The change in net benefits for the proposed regulations varies depending on the amount of environmental risk associated with wellbore integrity issues and unlined pits and the level of remediation costs associated with contamination events. Assuming low remediation costs and low environmental risks, the change in net benefits from the baseline is negative and ranges from −$25.63MM and −$30.20MM per year using a discount rate of 7% and between −$25.70MM and −$30.33MM per year using a discount rate of 3%. Assuming high remediation costs and high environmental risks, the change in net benefits is positive and ranges between $5.33MM and $6.28MM per year using a discount rate of 7% and between $5.35MM and $6.31MM per year using a discount rate of 3%.

Given the assumptions made and the fact that certain benefits were not quantified, the range of estimated outcomes could underestimate the actual net benefits, i.e., where net benefits are estimated to be negative, the net benefits would be greater (or less negative).

This analysis also does not capture the potential benefits associated with the disclosure of fracturing fluids. For example, disclosure might encourage operators to use fewer or safer chemicals in the hydraulic fracturing fluid. The public would benefit from increased knowledge about the fluids used. This transparency is also likely to benefit scientists, state and Federal agencies, and other organizations that study the potential impacts of well stimulation operations. The BLM would be able to make more informed resource decisions and respond effectively to events where environmental resources have been compromised.

Also, the variance language might also enable operators to reduce costs, in which case, these estimates may overestimate the actual costs and underestimate the change in net benefits.

It should be noted that the low cost and risk scenario results in negative net benefits while the high cost and risk scenario results in positive net benefits. The primary difference is not a result of the administrative or operational costs changing between the scenarios. Instead, the difference is due to the valuation of social benefits. If the assumed risk of contamination is greater and the costs of remediation are higher, then benefits of the proposed rule would be greater and offset the compliance costs.

The annual cost per well stimulation does not vary greatly between the cost and risk scenarios, but the benefits do. The average annual cost per well (including administrative and operational costs) is estimated to be about $11,833. However, the average annual benefit ranges more widely, between $3,754 and $13,688. The uncertainty about risk and damages causes this variability. The net benefit ranges from −$8,079 to $1,855 on a per well stimulation basis.

Note that the figures for the estimated benefits of the proposed rule do not include such benefits as avoiding harm to water users that cannot be compensated by later providing alternative water sources. The increase in information about additives could aid water users when they consider the potential effects of well stimulation operations and constituent chemicals.

Economic Impact Analysis and Distributional Assessments

Energy System Impact Analysis

Executive Order 13211 provides that agencies prepare and submit to the Administrator of the Office of Information and Regulatory Affairs (OIRA), OMB, a Statement of Energy Effects for certain actions identified as significant energy actions. Section 4(b) of Executive Order 13211 defines a ''significant energy action'' as ''any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of OIRA as a significant energy action.''

This analysis estimates the additional cost burden per well stimulation event and finds that the average burden per stimulation is about $11,833 in 2013.

The BLM believes that the additional cost per well stimulation resulting from this proposed rule is insignificant when compared with the drilling costs in recent years, the production gains from hydraulically fractured well operations, and the net incomes of entities within the oil and natural gas industries.

Table 4 presents drilling costs per well for a range of wells from 1998 to 2007. The data clearly show that drilling costs increased during this time. Using the estimates for the average burden per well stimulation and the average cost of drilling wells in 2007, the annual costs of this proposed rule represent about 0.3% of the drilling cost of a well.

As such, the proposed regulations are unlikely to have an effect on the investment decisions of firms, and the rule is unlikely to affect the supply, distribution, or use of energy.

TABLE 4—PER WELL COSTS OF CRUDE OIL AND NATURAL GAS WELLS DRILLED

Year	Crude oil, natural gas, and dry wells drilled (nominal $)	Crude oil wells drilled (nominal $)	Natural gas wells drilled (nominal $)
1998	769,100	566,000	815,600
1999	856,100	783,000	798,400
2000	754,600	593,400	756,900
2001	943,200	729,100	896,500
2002	1,054,200	882,800	991,900
2003	1,199,500	1,037,300	1,106,000
2004	1,673,100	1,441,800	1,716,400
2005	1,720,700	1,920,400	1,497,600
2006	2,101,700	2,238,600	1,936,200
2007	4,171,700	4,000,400	3,906,900

Source: Energy Information Administration (2012), ''Costs of Crude Oil and Natural Gas Wells Drilled''.

Employment Impact Analysis

Executive Order 13563 reaffirms the principles established in Executive Order 12866, but calls for additional consideration of the regulatory impact on employment. It states, ''Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.'' An analysis of employment impacts is a standalone analysis and the impacts should not be included in the estimation of benefits and costs.

This analysis seeks to inform the discussion of labor demand and job impacts by providing an estimate of the employment impacts of the proposed regulations using labor requirements for the additional administration and operational needs.

This proposed rule would require operators who have not already done so to conduct one-time tests on a well or make a one-time installation of a mitigation control feature. In addition, operators would be required to perform administrative tasks related to a one-time event. Compliance with the operational requirements would shift resources within the industry from the operators to firms providing the services or supplies. For example, the requirement for a cement bond log represents an additional cost to the operator, but a benefit to the company running the log.

In 2013, the BLM estimates that the labor requirements for operators to meet additional administrative and operational needs are estimated to be about 15 to 18 full time equivalents in each of the next three years. According to the U.S. Census Bureau, employment in the related sectors was 257,302 persons in 2007. Note that these impacts are only for the regulated sector. The BLM cannot predict the net national employment impact, i.e., whether the increased employment in the regulated sector comes from previously unemployed workers or is displaces workers actively employed in other sectors.

Another area of interest is the extent to which the financial burden is expected to change operators' investment decisions. If the financial burden is not significant and all other factors are equal, then one would expect operators to maintain existing levels of investment and employment. As with the results in the earlier discussion, the BLM believes that the proposed rule would result in an additional cost per well stimulation that is small and would not alter the investment or employment decisions of firms. Therefore, considering the labor requirements and those operators would not likely reduce investment, the BLM anticipates an overall net gain in employment in the sectors.

Executive Order 12866, Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, the Office of Management and Budget has determined that this rule is a significant regulatory action.

The rule will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. However, the rule may raise novel policy issues because of the proposed requirement that operators provide to the BLM information regarding well stimulation activities that they are not currently providing to the BLM.

This proposed rule would not create inconsistencies or otherwise interfere with an action taken or planned by another agency. This proposed rule would not change the relationships of the oil and gas operations with other agencies. These relationships are included in agreements and memoranda of understanding that would not change with this rule. In addition, this proposed rule would not materially affect the budgetary impact of entitlements, grants, loan programs, or the rights and obligations of their recipients. Please see the discussion of the impacts of the proposed rule as described earlier in this section of the preamble.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act of 1980 (RFA), as amended, 5 U.S.C. 601–612, to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. For the purposes of this analysis, we will assume that all entities (all lessees and operators) that may be affected by this proposed rule are small entities, even though that is not actually the case.

The proposed rule deals with well stimulation on all Federal and Indian lands (except those excluded by statute). There would be some increased costs associated with the proposed enhanced

recordkeeping requirements and some new operational requirements. However, the BLM expects that these costs would be minor in comparison to overall operations costs. Therefore, the BLM has determined under the RFA that the proposed rule would not have a significant economic impact on a substantial number of small entities. Please see the discussion earlier in this section of the preamble for a discussion of the impacts of the rule.

Small Business Regulatory Enforcement Fairness Act

The Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small governmental jurisdictions, or small not-for-profit enterprises.

The BLM reviewed the Small Business Administration (SBA) size standards for small businesses and the number of entities fitting those size standards as reported by the U.S. Census Bureau in the 2007 Economic Census. Using the Economic Census data, the BLM concludes that about 99% of the entities operating in the relevant sectors are small businesses in that they employ fewer than 500 employees. Also, small firms account for 74% of the total value of shipments and receipts for services, 86% of the total cost of supplies, 78% of the total capital expenditures (excluding land and mineral rights), and 67% of the paid employees.

Small entities represent the overwhelming majority of entities operating in the onshore crude oil and natural gas extraction industry. As such, the proposed rule is likely to affect a significant number of small entities. To examine the economic impact of the rule on small entities, the BLM performed a screening analysis for impacts on a sample of expected affected small entities by comparing compliance costs to entity net incomes.

Under the cost and risk scenarios, the average cost per entity in 2013 is estimated to represent between 0.002% and 0.22% of the 2010 net incomes of the sampled companies, depending on the U.S. Energy Information Administration's Annual Energy Outlook commodity price forecasts. The proportions do not change substantially over the outlook period.

After considering the economic impact of the proposed rule on these small entities, the screening analysis indicates that this proposed rule would not have a significant economic impact on a substantial number of small entities. Please see the discussion earlier in this section of the preamble for a discussion of the impacts of the rule.

Unfunded Mandates Reform Act

This proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate, or to the private sector in any one year. Thus, the proposed rule is also not subject to the requirements of Sections 202 or 205 of the Unfunded Mandates Reform Act (UMRA).

This proposed rule is also not subject to the requirements of Section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments; it contains no requirements that apply to such governments nor does it impose obligations upon them.

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

Under Executive Order 12630, the proposed rule would not have significant takings implications. A takings implication assessment is not required. This proposed rule would establish recordkeeping requirements for hydraulic fracturing operations and some additional operational requirements on Federal and Indian lands. All such operations are subject to lease terms which expressly require that subsequent lease activities be conducted in compliance with subsequently adopted Federal laws and regulations. The proposed rule conforms to the terms of those Federal leases and applicable statutes, and as such the proposed rule is not a governmental action capable of interfering with constitutionally protected property rights. Therefore, the proposed rule would not cause a taking of private property or require further discussion of takings implications under this Executive Order.

Executive Order 13352, Facilitation of Cooperative Conservation

Under Executive Order 13352, the BLM has determined that this proposed rule would not impede facilitating cooperative conservation and would take appropriate account of and consider the interests of persons with ownership or other legally recognized interests in land or other natural resources. This rulemaking process will involve Federal, State, local and tribal governments, private for-profit and nonprofit institutions, other nongovernmental entities and individuals in the decision-making. The process would provide that the programs, projects, and activities are consistent with protecting public health and safety.

Executive Order 13132, Federalism

Under Executive Order 13132, this proposed rule would not have significant Federalism effects. A Federalism assessment is not required because the proposed rule would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The proposed rule would not have any effect on any of the items listed. The proposed rule would affect the relationship between operators, lessees, and the BLM, but would not impact states. Therefore, under Executive Order 13132, the BLM has determined that the proposed rule would not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13175, the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), and 512 Departmental Manual 2, the BLM evaluated possible effects of the proposed rule on federally recognized Indian tribes. The BLM approves proposed operations on all Indian onshore oil and gas leases (except those excluded by statute). Therefore, the proposed rule has the potential to affect Indian tribes. In conformance with the Secretary's policy on tribal consultation, the Bureau of Land Management held four tribal consultation meetings to which over 175 tribal entities were invited. The consultations were held in:

- Tulsa, Oklahoma on January 10, 2012;
- Billings, Montana on January 12, 2012;
- Salt Lake City, Utah on January 17, 2012; and
- Farmington, New Mexico on January 19, 2012.

The purpose of these meetings was to solicit initial feedback and preliminary comments from the tribes. Comments

from tribes will be received and consultation will continue as this rulemaking proceeds. To date, the tribes have expressed concerns about the BLM's Inspection and Enforcement program's ability to enforce the terms of this rule; previously plugged and abandoned wells being potential conduits for contamination of ground water; and the operator having to provide documentation that the water used for the fracturing operation was legally acquired. The BLM will further address these concerns during the drafting of the final rule.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the Office of the Solicitor has determined that the proposed rule would not unduly burden the judicial system and meets the requirements of Sections 3(a) and 3(b)(2) of the Order. The Office of the Solicitor has reviewed the proposed rule to eliminate drafting errors and ambiguity. It has been written to minimize litigation, provide clear legal standards for affected conduct rather than general standards, and promote simplification and avoid unnecessary burdens.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521) provides that an agency may not conduct or sponsor, and a person is not required to respond to, a ''collection of information,'' unless it displays a currently valid control number. Collections of information include requests and requirements that an individual, partnership, or corporation obtain information, and report it to a Federal agency (44 U.S.C. 3502(3); 5 CFR 1320.3(c) and (k)).

In accordance with the PRA, the BLM is inviting public comment on its request that OMB assign a new control number for proposed new uses of Form 3160–5 (Sundry Notices and Reports on Wells). The BLM is proposing that these new uses would replace certain existing uses of Form 3160–5 for well-stimulation operations.

OMB has approved the use of Form 3160–5 under control number 1004–0137, Onshore Oil and Gas Operations (43 CFR part 3160) to collect information on a number of operations, including some well-stimulation operations. Once the BLM is authorized to collect well-stimulation information in accordance with finalized new section 3162.3–3 and a new control number, the BLM will request revision of control number 1004–0137 to:

- Add the new well-stimulation uses and burdens of Form 3160–5 to control number 1004–0137, and
- Remove the existing well-stimulation uses and burdens from the existing approval of Form 3160–5.

The new collection of information would be required to obtain or retain a benefit for the operators of Federal and Indian (except on the Osage Reservation, the Crow Reservation, and certain other areas) onshore oil and gas leases, units, or communitization agreements that include Federal leases. The BLM has requested a 3-year term of approval for the new control number.

The information collection request for this proposed rule has been submitted to OMB for review under 44 U.S.C. 3504(h) of the Paperwork Reduction Act. A copy of the request can be obtained from the BLM by electronic mail request to Barbara Gamble at *barbara_gamble@blm.gov* or by telephone request to 202–912–7148. The BLM requests comments to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Comments on the information collection requirements should be sent to both OMB and the BLM as directed in the **ADDRESSES** section of this preamble. OMB is required to make a decision concerning the collection of information contained in this proposed rule between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it by June 11, 2012.

Summary of Information Collection Requirements

The proposed rule is intended to increase transparency for the public regarding the fluids and additives used in well stimulation. The proposed provisions that include information collection requirements are amendments to 43 CFR 3162.3–2 new 43 CFR 3162.3–3.

OMB has approved the use of Form 3160–5 under control number 1004–0137 for the operations listed in existing section 3162.3–2. As amended, section 3162.3–2 would no longer include well stimulation jobs (i.e., nonroutine fracturing, routine fracturing, and acidizing) on the list of operations for which prior approval and subsequent reports would be required. Other categories of operations would remain subject to the information collection requirements in section 3162.3–2. Once the BLM is authorized to collect well-stimulation information under new section 3162.3–3 and a new control number, the BLM will request revision of control number 1004–0137 by removing the well-stimulation burdens from the existing approval of Form 3160–5. New section 3162.3–3 would require operators to use Form 3160–5 both to seek prior BLM approval of well stimulation operations, and to submit a report on subsequent actual well stimulation operations. It would also encourage operators to use Form 3160–5 if they want to request a variance from the requirements of new section 3162.3–3.

Request for Prior Approval (i.e., Notice of Intent Sundry)

New section 3162.3–3(b) would require operators to seek and obtain prior approval by the BLM for proposed well stimulation operations. Submission of the information, called a Notice of Intent (NOI) Sundry in the proposed rule, would be required at least 30 days before the date the operator wants to begin well stimulation operations. The information to be included in this Notice of Intent Sundry, and the reasons for requiring it, are listed in the following table:

Proposed regulation 43 CFR	Proposed regulatory text	Rationale
§ 3162.3–3(c)(1)	The geological names, a geological description, and the proposed measured depth of the top and the bottom of the formation into which well stimulation fluids are to be injected.	The BLM would use the information to determine the properties of the rock layers and the thickness of the producing formation, and identify the confining rocks above and below the zone that would be stimulated.

Proposed regulation 43 CFR	Proposed regulatory text	Rationale
§ 3162.3–3(c)(2)	The proposed measured depths (both top and bottom) of all occurrences of usable water and the Cement Bond Logs (or another log acceptable to the authorized officer) proving that the occurrences of usable water have been isolated to protect them from contamination.	The BLM would use the information to help protect water resources.
§ 3162.3–3(c)(3)	The proposed measured depth of perforations or the open-hole interval, the source and location(s) of the water used in the stimulation fluid or trade name of the base fluid (if other than water), type of proppants, and estimated pump pressures. Information concerning water supply, such as rivers, creeks, springs, lakes, ponds, and wells, which may be shown by quarter-quarter section on a map or plat, or which may be described in writing. The NOI Sundry must also identify the source, access route, and transportation method for all water anticipated for use in stimulating the well.	The BLM would use the information to determine the impacts associated with operations and the need for any mitigation applicable to Federal and Indian lands.
§ 3162.3–3(c)(4)	A certification signed by the operator that the proposed treatment fluid complies with all applicable permitting and notice requirements as well as all applicable Federal, tribal, state, and local laws, rules, and regulations.	The BLM would use the information to make an informed decision on the proposed well stimulation.
§ 3162.3–3(c)(5)	A detailed description of the proposed well stimulation design, including: (i) The estimated total volume of fluid to be used; (ii) The anticipated surface treating pressure range; (iii) The maximum injection treating pressure; and (iv) the estimated or calculated fracture length and fracture height	The information would enable the BLM to verify that the proposed engineering design is adequate for safely conducting the proposed well stimulation, that the maximum wellbore design burst pressure will not be exceeded at any stage of the well stimulation operations, and that the intended effects of the well stimulation operation will remain confined to the petroleum-bearing rock layers and will not have unintended consequences for other rock layers, such as aquifers.
§ 3162.3–3(c)(6)	The following information concerning the handling of recovered fluids: (i) The estimated volume of fluid to be recovered during flow back, swabbing, and recovery from production facility vessels; (ii) The proposed methods of handling the recovered fluids, including, but not limited to, pit requirements, chemical composition of the fluid, pipeline requirements, holding pond use, re-use for other stimulation activities, or injection; and (iii) The proposed disposal method of the recovered fluids, including, but not limited to, injection, hauling by truck, or transporting by pipeline	The BLM would use the information to ensure that the facilities needed to process or contain the estimated volume of fluid will be available on location, that the handling methods will adequately ensure protection of public health and safety, and that the BLM has all necessary information regarding disposal of chemicals used, in the event it is needed to protect the environment and human health and safety and to prevent unnecessary or undue degradation of the public lands.
§ 3162.3–3(c)(7)	Additional information, as requested by the authorized officer.	The information would allow the BLM to make an informed decision about the proposed well stimulation if special circumstances exist.

Subsequent Report (i.e., Subsequent Report Sundry Notice)

Within 30 days after the completion of well stimulation operations, section 3162.3–3(f) of the proposed rule would require operators to submit a Subsequent Report Sundry Notice on Form 3160–5 (Sundry Notices and Report on Wells). The information to be included in this Subsequent Report, and the reasons for requiring it, are listed in the following table.

Proposed regulation 43 CFR	Proposed regulatory text	Rationale
§ 3162.3–3(e)(1)	A continuous record of the annulus pressure must be submitted with the required Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells) identified in paragraph (g) of this section.	The BLM would use the information to ensure that well stimulation activities are conducted as designed. The information would also show that stimulation fluids are going to the formation for which they were intended.

Proposed regulation 43 CFR	Proposed regulatory text	Rationale
§ 3162.3–3(e)(2)	If during the stimulation the annulus pressure increases by more than 500 pounds per square inch as compared to the pressure immediately preceding the stimulation, the operator must orally notify the authorized officer as soon as practicable, but no later than 24 hours following the incident. Within 15 days after the occurrence, the operator must submit a report containing all details pertaining to the incident, including corrective actions taken, as part of a Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells).	The BLM would use the information to ensure that stimulation fluids are going into the formation for which they were designed. The BLM also needs to obtain reasonable assurance that other resources are adequately protected.
§ 3162.3–3(g)(1)	The actual measured depth of perforations or the open-hole interval, the source and location(s) of the water used in the stimulation fluid or trade name of base fluid (if other than water), type of proppants, and estimated pump pressures. Information concerning water supply, such as rivers, creeks, springs, lakes, ponds, and wells, which may be shown by quarter-quarter section on a map or plat, or which may be described in writing. It must also identify the source, access route, and transportation method for all water used in stimulating the well.	The BLM would use the information to determine the impacts associated with operations and the need for any mitigation applicable to Federal and Indian lands.
§ 3162.3–3(g)(2)	The actual total volume of the fluid used	The BLM would use the information to maintain a record of the stimulation operation as actually performed.
§ 3162.3–3(g)(3)	The actual surface pressure and rate at the end of each fluid stage, and the actual flush volume, rate, and final pump pressure.	The BLM would use the information to ensure that the maximum allowable pressure has not been exceeded at any stage of the well stimulation operation.
§ 3162.3–3(g)(4) and (5)	(4) A report (table) that discloses all additives of the actual stimulation fluid, by additive trade name and purpose (such as, but not limited to, acid, biocide, breaker, brine, corrosion inhibitor, crosslinker, demulsifier, friction reducer, gel, iron control, oxygen scavenger, pH adjusting agent, proppant, scale inhibitor, or surfactant); and. (5) A report (table) that discloses the complete chemical makeup of all materials used in the actual stimulation fluid without regard to original source additive (see paragraph (g)(4) of this section). For each chemical, the operator must provide the Chemical Abstracts Service Registry Number as well as the percentage by mass. The percent mass value is the mass value for each component (Mc) divided by the value of the entire fluid mass (Mt) times 100. (Mc/Mt)*100 = percent value. The percent mass values should be for the entire stimulation operation, not for the individual stages.	The BLM would use the information to maintain a record of the stimulation operation as performed.
§ 3162.3–3(g)(6)	The actual, estimated, or calculated fracture length and fracture height.	The BLM would use the information to verify that the intended effects of the well stimulation operation remain confined to the petroleum-bearing rock layers and will not have unintended consequences on other rock layers or aquifers.
§ 3162.3–3(g)(7)	The Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells) may be completed in whole or in part, as applicable, by attaching the service contractor's job log or other report, so long as the information required in paragraphs (g)(1) through (g)(6) of this section is complete and readily apparent.	This provision would allow the operator the flexibility to submit a copy of the service company contractor's job log or other report in lieu of all or part of the data described above, so long as the required information is complete and readily apparent.
§ 3162.3–3(g)(8)	A certification signed by the operator that the treatment fluid used complies with all applicable permitting and notice requirements as well as all applicable Federal, tribal, state, and local laws, rules, and regulations.	The BLM would use the information to help protect public health and safety and obtain the operator's self-certification of compliance with all necessary permits and notice requirements.
§ 3162.3–3(g)(9)	A certification signed by the operator that wellbore integrity was maintained throughout the operation, as required by paragraphs (d), (e)(1), and (e)(2) of this section.	The BLM would use the information to help protect public health and safety and obtain the operator's self-certification that wellbore integrity was maintained throughout the operation.

Proposed regulation 43 CFR	Proposed regulatory text	Rationale
§ 3162.3–3(g)(10)	The following information concerning the handling of recovered fluids: (i) The volume of fluid recovered during flow back, swabbing, or recovery from production facility vessels; (ii) The methods of handling the recovered fluids, including, but not limited to, pipeline requirements, holding pond use, re-use for other stimulation activities, or injection; and (iii) The disposal method of the recovered fluids, including, but not limited to, injection, hauling by truck, or transporting by pipeline. The disposal of fluids produced during the flow back from the well stimulation process must follow the requirements set out in Onshore Order Number 7, Disposal of Produced Water, Section III. B.	The BLM would use the information to help protect human health and safety and prevent the contamination of the environment. The BLM also needs to confirm that the disposal methods used are those that were approved and conform to the regulations.
§ 3162.3–3(g)(11)	If the actual operations deviate from the approved plan, the deviation(s) must be documented.	The BLM would use the information to maintain a record of any deviations of the operation from the approved plan in the event such information is needed to protect health and safety and prevent undue degradation of the environment.

Requesting a Variance

Proposed 43 CFR 3162.3–3(j) would encourage operators to use Form 3160–5 to request a variance from the requirements under proposed section 3162.3–3. Any request for a variance, whether filed on Form 3160–5 or not, would have to specifically identify the regulatory provision of this section for which the variance is being requested, explain the reason the variance is needed, and demonstrate how the operator would satisfy the objectives of the regulation for which the variance is being requested.

Estimated Annual Hour and Cost Burdens

The estimated annual hour and costs burdens of each aspect of this information collection are shown in the following table:

A. Type of response	B. Number of responses	C. Hours per response	D. Total hours (column B × column C)
Sundry Notices and Reports on Wells/Well Stimulation/Notice of Intent Sundry, (43 CFR 3162.3–3), Form 3160–5	1,700	8	13,600
Sundry Notices and Reports on Wells/Well Stimulation/Subsequent Report, Sundry Notice, (43 CFR 3162.3–3, Form 3160–5	1,700	8	13,600
Sundry Notices and Reports on Wells/Well Stimulation/Variance Request, (43 CFR 3162.3–3), Form 3160–5	170	8	1,360
Totals	3,570	.....	28,560

National Environmental Policy Act

The BLM has prepared an environmental assessment (EA) that concludes that the proposed rule would not constitute a major Federal action that may result in a significant adverse effect on the human environment under section 102(2)(C) of the National Environmental Policy Act (NEPA), 42 U.S.C. 4332(2)(C). A detailed statement under NEPA would not be required if the proposed amendments were promulgated as regulations. The BLM has placed the EA and the draft Finding of No Significant Impact on file in the BLM Administrative Record at the address specified in the **ADDRESSES** section.

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

In accordance with Executive Order 13211, the BLM has determined that the proposed rule will not have substantial direct effects on the energy supply, distribution, or use, including a shortfall in supply or price increase. Please see the discussion earlier in this section of the preamble for a discussion of the impacts of the rule.

Clarity of the Regulations

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. We invite your comments on how to make these proposed regulations easier to understand, including answers to questions such as the following:

1. Are the requirements in the proposed regulations clearly stated?

2. Do the proposed regulations contain technical language or jargon that interferes with their clarity?

3. Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?

4. Would the regulations be easier to understand if they were divided into more (but shorter) sections?

5. Is the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble helpful in understanding the proposed regulations? How could this description be more helpful in making the proposed regulations easier to understand?

Please send any comments you have on the clarity of the regulations to the address specified in the **ADDRESSES** section.

Authors

The principal authors of this rule are: Michael Worden of the BLM Washington Office; Nicholas Douglas of BLM Washington Office; Adrienne Brumley of the BLM New Mexico State Office; Donato Judice of the BLM Great Falls, Montana Oil and Gas Field Office, assisted by Ian Senio and Joe Berry of the BLM's Division of Regulatory Affairs and the Department of the Interior's Office of the Solicitor.

List of Subjects

43 CFR Part 3160

Administrative practice and procedure; Government contracts; Indians—lands; Mineral royalties; Oil and gas exploration; Penalties; Public lands—mineral resources; Reporting and recordkeeping requirements.

43 CFR Chapter II

For the reasons stated in the preamble, and under the authorities stated below, the Bureau of Land Management proposes to amend 43 CFR part 3160 as follows:

PART 3160—ONSHORE OIL AND GAS OPERATIONS

1. The authorities citation for part 3160 is revised to read as follows:

Authority: 25 U.S.C. 396d and 2107; 30 U.S.C. 189, 306, 359 and 1751; 40 U.S.C. 4332, and 43 U.S.C. 1732(b), 1733, and 1740.

Subpart 3160—Onshore Oil and Gas Operations: General

§ 3160.0–3 [Amended]

2. In section 3160.0–3 add ''the Federal Land Policy and Management Act (43 U.S.C. 1701 *et seq.*),'' after ''the Mineral Leasing Act for Acquired lands, as amended (30 U.S.C. 351–359),''.

3. Amend § 3160.0–5 by adding definitions of ''annulus,'' ''bradenhead,'' ''proppant,'' ''stimulation fluid,'' ''usable water,'' and ''well stimulation'' in alphabetical order and by removing the definition of ''fresh water'':

The additions read as follows:

§ 3160.0–5 Definitions.

* * * * *

Annulus means the space around a pipe in a wellbore, the outer wall of which may be the wall of either the borehole or the casing; sometimes also called annular space.

* * * * *

Bradenhead means a heavy, flanged steel fitting connected to the first string of casing that allows suspension of intermediate and production strings of casing and supplies the means for the annulus to be sealed off.

* * * * *

Proppant means a granular substance (most commonly sand, sintered bauxite, or ceramic) that is carried in suspension by the fracturing fluid that serves to keep the cracks open when fracturing fluid is withdrawn after a hydraulic fracture treatment.

* * * * *

Stimulation fluid means the liquid or gas, including any associated solids, used during a treatment of oil and gas wells, such as the water, chemicals, and proppants used in hydraulic fracturing.

* * * * *

Usable water means generally those waters containing up to 10,000 ppm of total dissolved solids.

* * * * *

Well stimulation means those activities conducted in an individual well bore designed to increase the flow of hydrocarbons from the rock formation to the well bore through modifying the permeability of the reservoir rock. Examples of well stimulation operations are acidizing and hydraulic fracturing.

* * * * *

Subpart 3162—Requirements for Operating Rights Owners and Operators

4. Amend § 3162.3–2 by revising the first sentence of paragraph (a) and revising paragraph (b) to read as follows:

§ 3162.3–2 Subsequent well operations.

(a) A proposal for further well operations shall be submitted by the operator on Form 3160–5 for approval by the authorized officer prior to commencing operations to redrill, deepen, perform casing repairs, plug-back, alter casing, recomplete in a different interval, perform water shut off, commingling production between intervals and/or conversion to injection.

* * *

(b) Unless additional surface disturbance is involved and if the operations conform to the standard of prudent operating practice, prior approval is not required for recompletion in the same interval; however, a subsequent report on these operations must be filed on Form 3160–5.

* * * * *

5. Add a new § 3162.3–3 to read as follows:

§ 3162.3–3 Subsequent well operations; Well stimulation.

(a) This section applies to well stimulation activities. All other injection activities must comply with section 3162.3–2.

(b) *When an Operator Must Submit Notification for Approval of Well Stimulation.*

A proposal for well stimulation must be submitted by the operator and approved by BLM before commencement of operations. The proposal may be submitted in one of the following ways:

(i) For new wells, the operator may submit with its Application for Permit to Drill the information required in paragraph (c) of this section, except for the cement bond log required by paragraph (c)(2). The approved permit to drill will require submission and approval of the cement bond log required by paragraph (c)(2) prior to conducting well stimulation activities;

(ii) For wells permitted prior to the effective date of this section or for wells permitted after the effective date of this section, if the application for permit to drill a well did not include the information required in paragraph (c) of this section, the operator must submit a proposal for well stimulation operations on Form 3160–5 (Sundry Notices and Reports on Wells) as a Notice of Intent Sundry for approval by the authorized officer prior to well stimulation. If there is additional surface disturbance, the proposal must include a surface use plan of operations; and

(iii) If an operator has received BLM approval for well stimulation activities, it must submit a new Notice of Intent Sundry if either: (A) Well stimulation activities have not commenced within five years after the effective date of approval of the well stimulation activity; or (B) The operator has significant new information about the geology of the area, the stimulation operation or technology to be used, or the anticipated impacts of the stimulation activity to any resource.

(c) *What the Notice of Intent Sundry Must Include.* The authorized officer may prescribe that each proposal contain all or a portion of the information set forth in § 3162.3–1 of this title. The Notice of Intent Sundry must include the following:

(1) The geological names, a geological description, and the proposed measured depth of the top and the bottom of the formation into which well stimulation fluids are to be injected;

(2) The proposed measured depths (both top and bottom) of all occurrences of usable water and the cement bond logs (or another log acceptable to the authorized officer) proving that the occurrences of usable water have been isolated to protect them from contamination;

(3) The proposed measured depth of perforations or the open-hole interval, the source and location(s) of the water used in the stimulation fluid or trade name of the base fluid (if other than water), type of proppants, and estimated pump pressures. Information concerning water supply, such as rivers, creeks, springs, lakes, ponds, and wells, which may be shown by quarter-quarter section on a map or plat, or which may be described in writing. It must also identify the source, access route, and transportation method for all water anticipated for use in stimulating the well;

(4) A certification signed by the operator that the proposed treatment fluid complies with all applicable permitting and notice requirements as well as all applicable Federal, tribal, state, and local laws, rules, and regulations;

(5) A detailed description of the proposed well stimulation design, including:

(i) The estimated total volume of fluid to be used;

(ii) The anticipated surface treating pressure range;

(iii) The maximum injection treating pressure; and

(iv) The estimated or calculated fracture length and fracture height;

(6) The following information concerning the handling of recovered fluids:

(i) The estimated volume of fluid to be recovered during flow back, swabbing, and recovery from production facility vessels;

(ii) The proposed methods of handling the recovered fluids, including, but not limited to, pit requirements, chemical composition of the fluid, pipeline requirements, holding pond use, re-use for other stimulation activities, or injection; and

(iii) The proposed disposal method of the recovered fluids, including, but not limited to, injection, hauling by truck, or transporting by pipeline.

(7) The authorized officer may request additional information under this subsection prior to the approval of the Notice of Intent Sundry.

(d) *Mechanical Integrity Testing Prior to Well Stimulation.* Prior to the well stimulation, the operator must perform a successful mechanical integrity test (MIT) of the casing.

(1) If well stimulation through the casing is proposed, the casing must be tested to not less than the maximum anticipated treating pressure.

(2) If well stimulation through a fracturing string is proposed, the fracturing string must be inserted into a liner or run on a packer-set not less than 100 feet below the cement top of the production or intermediate casing. The fracturing string must be tested to not less than the maximum anticipated treating pressure minus the annulus pressure applied between the fracturing string and the production or intermediate casing.

(3) The MIT will be considered successful if the pressure applied holds for 30 minutes with no more than a 10 percent pressure loss.

(e)(1) *Monitoring and Recording During Well Stimulation.* During the well stimulation operation, the operator must continuously monitor and record the annulus pressure at the bradenhead. If an intermediate casing has been set on the well that is being stimulated, the pressure in the annulus between the intermediate casing and the production casing must also be continuously monitored and recorded. A continuous record of the annulus pressure during the well stimulation must be submitted with the required Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells) identified in paragraph (f) of this section.

(e)(2) If during the stimulation the annulus pressure increases by more than 500 pounds per square inch as compared to the pressure immediately preceding the stimulation, the operator must orally notify the authorized officer as soon as practicable, but no later than 24 hours following the incident. Within 15 days after the occurrence, the operator must submit a report containing all details pertaining to the incident, including corrective actions taken, as part of a Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells).

(f) Storage of all recovered fluids must be in either tanks or lined pits. The authorized officer may require additional measures to protect the mineral resources, other natural resources, and environmental quality from the release of recovered fluids.

(g) *Information that Must be Provided to the Authorized Officer After Completed Operations.* The following information must be provided to the authorized officer in the required Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells) within 30 days after the operations are completed (see subpart 3160.0–9(c)(1)):

(1) The actual measured depth of perforations or the open-hole interval, the source and location(s) of the water used in the stimulation fluid or trade name of base fluid (if other than water), type of proppants, and actual pump pressures. Information concerning water supply, such as rivers, creeks, springs, lakes, ponds, and wells, which may be shown by quarter-quarter section on a map or plat, or which may be described in writing. It must also identify the source, access route, and transportation method for all water used in stimulating the well;

(2) The actual total volume of the fluid used;

(3) The actual surface pressure and rate at the end of each fluid stage, and the actual flush volume, rate, and final pump pressure;

(4) A report (table) that discloses all additives of the actual stimulation fluid, by additive trade name and purpose (such as, but not limited to, acid, biocide, breaker, brine, corrosion inhibitor, crosslinker, demulsifier, friction reducer, gel, iron control, oxygen scavenger, pH adjusting agent, proppant, scale inhibitor, or surfactant);

(5) A report (table) that discloses the complete chemical makeup of all materials used in the actual stimulation fluid without regard to original source additive (see paragraph (f)(4) of this section). For each chemical, the operator must provide the Chemical Abstracts Service Registry Number as well as the percentage by mass. The percent mass value is the mass value for each component (Mc) divided by the value of the entire fluid mass (Mt) times 100. (Mc/Mt) * 100 = percent value. The percent mass values should be for the entire stimulation operation, not for the individual stages.

(6) The actual, estimated, or calculated fracture length and fracture height;

(7) The Subsequent Report Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells) may be completed in whole or in part, as applicable, by attaching the service contractor's job log or other report, so long as the information required in paragraphs (g)(1) through (g)(6) of this section is complete and readily apparent;

(8) A certification signed by the operator that the treatment fluid used complied with all applicable permitting and notice requirements as well as all applicable Federal, tribal, state, and local laws, rules, and regulations;

(9) A certification signed by the operator that wellbore integrity was maintained throughout the operation, as required by paragraphs (d), (e)(1), and (e)(2) of this section;

(10) The following information concerning the handling of recovered fluids:

(i) The volume of fluid recovered during flow back, swabbing, or recovery from production facility vessels;

(ii) The methods of handling the recovered fluids, including, but not limited to, pipeline requirements, holding pond use, re-use for other stimulation activities, or injection; and

(iii) The disposal method of the recovered fluids, including, but not limited to, injection, hauling by truck, or transporting by pipeline. The disposal of fluids produced during the flow back from the well stimulation process must follow the requirements set out in Onshore Order Number 7, Disposal of Produced Water, Section III.B. (October 8, 1993, 58 FR 47354).

(11) If the actual operations deviate from the approved plan, the deviation(s) must be documented and explained.

(h) *Identifying Information Claimed to be Exempt from Public Disclosure.* At the time of submission of any information required under this section, operators must:

(1) Specifically identify particular information claimed to be exempted from public disclosure by a Federal statute or regulation;

(2) Identify the Federal statute or regulation that prohibits the public disclosure of each piece of particular information, and explain in detail why the information is subject to the prohibition of the identified Federal statute or regulation; and

(3) Inform the BLM whether the particular information is available to the public through other means, such as disclosures required by state law.

(i) Any information that is provided in accordance with this section for which the operator does not substantiate a reason for withholding under paragraph (h) of this section shall be deemed not to be protected by the Trade Secrets Act or other Federal law and shall be released to the public. If an operator identifies information as exempt from disclosure, the BLM may nonetheless release that information if it determines that the information is not prohibited from disclosure by Federal law, after providing the operator with no fewer than 10 business days notice of the BLM's determination.

(j) *Requesting a Variance from the Requirements of this Section.* The operator may make a written request to the authorized officer to request a variance from the requirements under this section. The BLM encourages submission using a Sundry Notice (Form 3160–5, Sundry Notices and Reports on Wells).

(1) A request for a variance must specifically identify the regulatory provision of this section for which the variance is being requested, explain the reason the variance is needed, and demonstrate how the operator will satisfy the objectives of the regulation for which the variance is being requested.

(2) The authorized officer, after considering all relevant factors, may approve the variance, or approve it with one or more conditions of approval, only if the BLM determines that the proposed alternative meets or exceeds the objectives of the regulation for which the variance is being requested. The decision whether to grant or deny the variance request is entirely within the BLM's discretion.

(3) A variance under this section does not constitute a variance to provisions of other regulations, laws, or orders.

(4) Due to changes in Federal law, technology, regulation, BLM policy, field operations, noncompliance, or other reasons, the BLM reserves the right to rescind a variance or modify any conditions of approval. The authorized officer must provide a written justification if a variance is rescinded or a condition of approval is modified.

6. Amend § 3162.5–2 by revising the first sentence of paragraph (d) to read as follows:

§ 3162.5–2 Control of wells.

* * * * *

(d) *Protection of usable water and other minerals.* The operator shall isolate all usable water and other mineral-bearing formations and protect them from contamination. Tests and surveys of the effectiveness of such measures shall be conducted by the operator using procedures and practices approved or prescribed by the authorized officer. * * *

Dated: May 4, 2012.

Marcilynn Burke,

Acting Assistant Secretary, Land and Minerals Management.

[FR Doc. 2012–11304 Filed 5–10–12; 8:45 am]

BILLING CODE P

Notices

Federal Register

Vol. 77, No. 92

Friday, May 11, 2012

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0015]

Notice of Request for Revision and Extension of Approval of an Information Collection; National Veterinary Accreditation Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a revision and extension of approval of an information collection associated with the National Veterinary Accreditation Program.

DATES: We will consider all comments that we receive on or before July 10, 2012.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0015-0001*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2012–0015, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0015* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the National Veterinary Accreditation Program, contact Dr. Todd Behre, Veterinary Medical Officer, National Veterinary Accreditation Program, VS, APHIS, 4700 River Road, Riverdale, MD 20737; (301) 851–3401. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

SUPPLEMENTARY INFORMATION:

Title: National Veterinary Accreditation Program.

OMB Number: 0579–0297.

Type of Request: Revision and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 et seq.), the Secretary of Agriculture is authorized to protect the health of U.S. livestock by preventing the introduction and interstate spread of serious diseases and pests of livestock and for eradicating such diseases from the United States when feasible. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS). In connection with this mission, the U.S. Department of Agriculture established the National Veterinary Accreditation Program (NVAP) so that accredited private practitioners can assist Federal veterinarians in controlling animal diseases and facilitating the movement of animals. Regulations concerning the accreditation of veterinarians and the suspension and revocation of accreditation are in 9 CFR, chapter I, subchapter J (parts 160 through 162).

In 2010, APHIS amended its regulations dealing specifically with the requirements and standards for accredited veterinarians and the suspension and revocation of accreditation. As part of these amendments, APHIS established two accreditation categories in place of the previous single category; required accredited veterinarians to complete supplemental training modules, required accredited veterinarians to obtain written approval from APHIS before performing accredited duties in a different State, and required renewal of accreditation every 3 years. These changes were designed to increase the training and awareness of accredited veterinarians regarding disease surveillance, disease prevention, and preparedness for animal health emergencies in the United States. These requirements involve the use of the VS Form 1–36A.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.50 hours per response.

Respondents: Veterinarians.

Estimated annual number of respondents: 23,800.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 23,800.

Estimated total annual burden on respondents: 11,900 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 7th day of May 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012–11416 Filed 5–10–12; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA), that a planning meeting of the Connecticut State Advisory Committee will convene at 10:30 a.m. on Friday, May 25, 2012 at the University of Connecticut, School of Law, Faculty Lounge, 55 Elizabeth Street, Hartford, CT 06105. The purpose of the planning meeting is for review and approval of Advisory Committee report.

Members of the public are entitled to submit written comments; the comments must be received in the regional office by Monday, June 25, 2012. Comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 624 9th Street NW., Suite 740, Washington, DC 20425, faxed to (202) 376–7548, or emailed to *ero@usccr.gov.* Persons who desire additional information should contact the Eastern Regional Office at 202–376–7533.

Persons needing accessibility services should contact the Eastern Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from these meetings may be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Eastern Regional Office at the above email or street address or phone number.

The meetings will be conducted pursuant to the rules and regulations of the Commission and FACA.

Dated in Washington, DC, May 8, 2012.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2012–11375 Filed 5–10–12; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of Industry and Security (BIS).

Title: Statement by Ultimate Consignee and Purchaser.

OMB Control Number: 0694–0021.

Form Number(s): BIS–711.

Type of Request: Regular submission (extension of a currently approved information collection).

Burden Hours: 39.

Number of Respondents: 147.

Average Hours per Response: 16 minutes.

Needs and Uses: This collection is required by Section 748.11 of the Export Administration Regulations (EAR). The Form BIS–711 or letter puts the importer on notice of the special nature of the goods proposed for export and conveys a commitment against illegal disposition. In order to effectively control commodities, BIS must have sufficient information regarding the end-use and end-user of the U.S. origin commodities to be exported. The information will assist the licensing officer in making the proper decision on whether to approve or reject the application for the license.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Required to obtain benefits.

OMB Desk Officer: Jasmeet Seehra, FAX number (202) 395–7285.

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Jasmeet Seehra, OMB Desk Officer, by email to *Jasmeet_K._Seehra@omb.eop.gov*, or by fax to (202) 395–5167.

Dated: May 7, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–11370 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Feedback Survey for Semi-Annual Tsunami Warning Communications Test.

OMB Control Number: 0648–0539.

Form Number(s): NA.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 300.

Average Hours per Response: 5 minutes.

Burden Hours: 25.

Needs and Uses: This request is for extension of a current information collection.

This information collection supports the Tsunami Warning and Education Act, Public Law 109–424. To assess the effectiveness of NOAA/National Weather Service's (NWS) Tsunami Warning System, this survey is needed to gather specific feedback information following testing of the associated NWS communications systems. The tests are conducted annually, in March/April and again in September. Post-test feedback information will be requested from emergency managers, the media, law enforcement officials, local government agencies/officials, and the general public. The responses will be solicited for a limited period immediately following completion of the tests, not to exceed seven days. This will be a Web-based survey and will allow for efficient collection of information regarding the effectiveness of the Tsunami Warning System.

Affected Public: Individuals or households, state, local and tribal governments.

Frequency: Semi-annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov*.

Copies of the above information collection proposal can be obtained by

calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov*.

Dated: May 8, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–11386 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–KE–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–35–2012]

Foreign-Trade Zone 220—Sioux Falls, SD; Application for Reorganization and Expansion Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Sioux Falls Development Foundation, grantee of FTZ 220, requesting authority to reorganize and expand the zone under the alternative site framework (ASF) adopted by the Board (15 CFR Sec. 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on May 7, 2012.

FTZ 220 was approved by the Board on April 8, 1997 (Board Order 882, 62 FR 18740, 04/17/1997). The current zone project includes the following sites: *Site 1* (130 acres)—Joe Foss Field, 2801 Jaycee Lane, Sioux Falls; *Site 2* (123 acres)—Sioux Falls Development Foundation Park III, 4th Avenue North, Sioux Falls; *Site 3* (115 acres)—Sioux Falls Development Foundation Park IV, East Benson Road and Interstate 229, Sioux Falls; *Site 4* (7 acres, 2 parcels)—Burns Moving & Storage Facility, 4205 North 4th Avenue and North 2nd Avenue and 54th Street, Sioux Falls; *Site 5* (7 acres, 2 parcels)—Parker Transfer and Storage, Inc., 1700 F Avenue and 3703 West Tickman Street, Sioux Falls; and, *Site 6* (10 acres)—Nordica Warehouse, Inc., 801 South 6th Avenue, Sioux Falls.

The grantee's proposed service area under the ASF would be Bon Homme, Brookings, Clay, Davison, Duel, Hamlin, Hanson, Hutchinson, Kingsbury, Lake, Lincoln, McCook, Miner, Minnehaha, Moody, Sanborn, Turner, Union and Yankton Counties, South Dakota, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The proposed service area is within and adjacent to the Sioux Falls U.S. Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone project to include existing Sites 1–3 as ''magnet'' sites and existing Site 4–6 as ''usage-driven'' sites. The ASF allows for the possible exemption of one magnet site from the ''sunset'' time limits that generally apply to sites under the ASF, and the applicant proposes that Site 2 be so exempted. As part of the reorganization under the ASF, the applicant is requesting authority to remove a non-contiguous parcel from Site 5 to create a new usage-driven site: *Proposed Site 7* (3.3 acres)—Parker Transfer and Storage, Inc., 3703 West Tickman Street, Sioux Falls. The applicant is also requesting approval of the following ''usage-driven'' site: *Proposed Site 8* (15.03 acres)—Rosenbauer America, LLC/Rosenbauer South Dakota, LLC, 100 Third Street, Lyons, South Dakota.

In accordance with the Board's regulations, Camille Evans of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is July 10, 2012. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to July 25, 2012.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.* For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: May 7, 2012.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2012–11471 Filed 5–10–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–920]

Lightweight Thermal Paper From the People's Republic of China: Rescission of the 2010–2011 Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* May 11, 2012.

FOR FURTHER INFORMATION CONTACT: Lindsey Novom and Brendan Quinn, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5256 and (202) 482–5848, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2011, the Department of Commerce (''Department'') published a notice of opportunity to request an administrative review of the antidumping duty order on lightweight thermal paper from the People's Republic of China (''PRC'').[1] The period of review (''POR'') is November 01, 2010, through October 31, 2011. On November 30, 2011, in accordance with 19 CFR 351.213(b), the Department received a timely request from Appleton Papers, Inc. (''Petitioner'') to conduct an administrative review of Shanghai Hanhong Paper Co., Ltd. and Hanhong International Limited (collectively ''Hanhong'') and Guangdong Guanhao High-Tech Co., Ltd. (''Guanhao''). In this case, there were no other requests for an administrative review by any other party.

Pursuant to this request, the Department published a notice of the initiation of the administrative review of

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 76 FR 67413 (November 1, 2011).

the antidumping duty order on LWTP from the PRC for the POR.[2]

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. In this case, on March 29, 2012, Petitioner timely withdrew its request for a review, and no other interested party requested a review of Hanhong or Guanhao. Therefore, the Department is rescinding the administrative review of the antidumping duty order on lightweight thermal paper from the PRC covering the period November 01, 2010, through October 31, 2011, in accordance with 19 CFR 351.213(d)(1).

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after the publication of this notice in the **Federal Register**.

Notification to Interested Parties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Pursuant to 19 CFR 351.402(f)(3), failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO, in accordance with 19 CFR 351.305 and as explained in the APO itself. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: May 4, 2012.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2012–11469 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 76 FR 82268 (December 30, 2011).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; International Billfish Angler Survey

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before July 10, 2012.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions can be directed to James Wraith, (858) 546–7087 or *james.wraith@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a current information collection.

The International Billfish Angler Survey began in 1969 and is an integral part of the Billfish Research Program at the National Oceanic and Atmospheric Administration's (NOAA) Southwest Fisheries Science Center (SWFSC). The survey tracks recreational angler fishing catch and effort for billfish in the Pacific and Indian Oceans in support of the Pacific and Western Pacific Fishery Management Councils, authorized under the Magnuson-Stevens Fishery Management and Conservation Act (MSA). The data are used by scientists and fishery managers to assist with assessing the status of billfish stocks. The survey is intended for anglers cooperating in the Billfish Program and is entirely voluntary. This survey is specific to recreational anglers fishing for Istiophorid and Xiphiid billfish in the Pacific and Indian Oceans; as such it provides the only estimates of catch per unit of effort for recreational billfish fishing in those areas.

II. Method of Collection

The paper form is sent to anglers with recent participation in the SWFSC Billfish Research Program and is also available for downloading on the SWFSC Billfish Program Web site. Completed forms are submitted by mail.

III. Data

OMB Control Number: 0648–0020.

Form Number: NOAA Form 88–10.

Type of Review: Regular submission (extension of a current information collection).

Affected public: Individuals or households.

Estimated Number of Respondents: 600.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 50.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 8, 2012.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2012–11449 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council's (Council) Herring Advisory Panel (AP) will meet to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Thursday, May 31, 2012 at 9:30 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn, One Newbury Street, Route 1, Peabody, MA 01960; telephone: (978) 535–4600; fax: (978) 535–8238.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The items of discussion in the Advisory Panel's agenda are as follows:

1. The Herring Advisory Panel will meet to review and discuss the public hearing document and Draft Environmental Impact Statement (DEIS) for Amendment 5 to the Atlantic Herring Fishery Management Plan (FMP);
2. The AP will develop recommendations for the Herring Committee and Council to consider during the selection of final management measures for Amendment 5;
3. If necessary, other business will be addressed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 8, 2012.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2012–11381 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Fishery of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 31 Gulf of Mexico red snapper (*Lutjanus Campechanus*) data scoping assessment process webinar.

SUMMARY: The SEDAR 31 assessment of the Gulf of Mexico red snapper fishery will consist of a series of workshops and supplemental webinars. This notice is for a webinar associated with the Data portion of the SEDAR process. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 31 Data Workshop data scoping webinar will be held on July 11, 2012, 1 p.m. to 5 p.m. EST. The established time may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from, or completed prior to the times established by this notice.

ADDRESSES: The webinar will be held via a GoToMeeting Webinar Conference. The webinar is open to members of the public. Those interested in participating should contact Ryan Rindone at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request meeting information at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, SEDAR Coordinator, 2203 N Lois Ave, Suite 1100, Tampa FL 33607; telephone: (813) 348–1630; email: *ryan.rindone@gulfcouncil.org.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico Fishery Management Council, in conjunction with NOAA Fisheries, has implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop, (2) Assessment Process including a workshop and webinars, (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting Panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico Fishery Management Council, NOAA Fisheries Southeast Regional Office, and NOAA Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

SEDAR 31 Data Workshop data scoping webinar:

Participants will determine red snapper data sets deemed appropriate for consideration for use in the stock assessment process. All known and available data sets may be offered for consideration. Preliminary decisions with respect to the utility of each data set will be made during the data scoping webinar, and participant recommendations will be forwarded along to the Data Workshop (to be held at a later date).

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **FOR FURTHER INFORMATION CONTACT**) at least 10 business days prior to the meeting.

Dated: May 8, 2012.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2012–11448 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council's (Council) Groundfish Committee will meet to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Wednesday, May 30, 2012 at 9 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn, 31 Hampshire Street, Mansfield, MA 02048; telephone: (508) 339–2200; fax: (508) 339–1040.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The items of discussion in the committee's agenda are as follows:

The Groundfish Oversight Committee will discuss possible adjustments to sector management measures and issues related to setting Acceptable Biological Catches (ABCs), Annual Catch Limits (ACLs), and Accountability Measures (AMs). After receiving reports from the Groundfish Advisory Panel and the Recreation Advisory Panel, the Committee will continue to develop options to improve sector monitoring, including both at-sea and dockside monitoring. They may discuss different funding mechanisms, appropriate coverage levels, and full retention of allocated groundfish species. With respect to ABCs/ACLs/AMs, the Committee will consider additional sub-ACLs for the scallop fishery for stocks such as SNE/MAB windowpane flounder and SNE/MA winter flounder. As directed in the letter from the National Marine Fisheries Service approving Framework 47, Committee members will also discuss additional reactive AMs for wolffish, SNE/MA winter flounder, and Atlantic halibut. The Committee may begin a discussion of recreational fishing measures for FY 2013. Options identified by the Committee will be included in a future management action or actions that will be considered by the Council in the fall of 2012. The Committee may also discuss other business, such as issues related to Georges Bank yellowtail flounder management.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 8, 2012.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2012–11380 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XB173

Marine Mammals; File No. 16919

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Eye of the Whale (Olga von Ziegesar, Responsible Party and Principal Investigator), P.O. Box 15191, Fitz Creek, AK 99603, has applied in due form for a permit to conduct research on humpback whales (*Megaptera novaeangliae*).

DATES: Written, telefaxed, or email comments must be received on or before June 11, 2012.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the *Features* box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 16919 from the list of available applications.

These documents are also available upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907) 586–7221; fax (907) 586–7249.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division at the above address. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Carrie Hubard, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226).

The applicant requests a five-year scientific research permit to continue a long-term census of humpback whales in Prince William Sound and adjacent waters of Alaska. Up to 200 takes for close vessel approach, photo-identification and behavioral observation of whales is requested annually to better define abundance, distribution, reoccurrence of old individuals vs. new individuals, feeding habits, vital rates, associations between animals, and sex of individual whales.

A draft environmental assessment (EA) has been prepared in compliance

with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), to examine whether significant environmental impacts could result from issuance of the proposed scientific research permit. The draft EA is available for review and comment simultaneous with the scientific research permit application.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 8, 2012.

Tammy C. Adams,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–11525 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA172

Marine Mammals; File No. 15453

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that a permit has been issued to the Waikiki Aquarium, 2777 Kalakaua Avenue, Honolulu, HI 96815 (Dr. Andrew Rossiter, Responsible Party), to conduct research on and enhancement of captive Hawaiian monk seals (*Monachus schauinslandi*).

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Pacific Islands Region, NMFS, 1601 Kapiolani Boulevard, Room 1110, Honolulu, HI 96814–4700; phone (808) 944–2200; fax (808) 973–2941.

FOR FURTHER INFORMATION CONTACT: Amy Sloan or Jennifer Skidmore, (301)427–8401.

SUPPLEMENTARY INFORMATION: On January 27, 2011, notice was published in the **Federal Register** (76 FR 4867) that a request for a permit to conduct research on and enhancement of the species identified above had been submitted by the above-named applicant. On May 24, 2011, notice was published in the **Federal Register** (76 FR 30109) that a request to amend the application had been submitted by the applicant to increase the number of seals to be maintained under the proposed permit (from two to three seals). The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Permit No. 15453 authorizes the Waikiki Aquarium to maintain in captivity up to three non-releasable Hawaiian monk seals for research and enhancement purposes. Research includes (1) a long-term study on the digestive efficiency of captive seals; and (2) a post-vaccination antibody response study using West Nile virus and canine distemper virus vaccinations. The seals will be displayed to the public incidental to the research program, and the Waikiki Aquarium provides daily public narrations and educational graphics about the Hawaiian monk seal. The permit is valid for five years from the date of issuance.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, issuance of this permit was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: April 30, 2012.

Tammy C. Adams,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–11523 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA873

Endangered Species; File No. 15566

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit modification.

SUMMARY: Notice is hereby given that South Carolina Department of Natural Resources, Marine Resources Division, Charleston, SC 29422–2559 [Responsible Party: Mike Arendt] has been issued a modification to scientific research Permit No. 15566.

ADDRESSES: The modification and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Southeast Region, NMFS, 263 13th Ave South, St. Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

FOR FURTHER INFORMATION CONTACT: Kristy Beard or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On December 20, 2011, notice was published in the **Federal Register** (76 FR 78890) that a modification of Permit No. 15566 had been requested by the above-named organization. The requested modification has been granted under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226).

Permit No. 15566, issued April 8, 2011 (76 FR 22877), authorizes capture by trawl of 345 loggerhead (*Caretta caretta*), 29 Kemp's ridley (*Lepidochelys kempii*), 9 green (*Chelonia mydas*), 1 leatherback (*Dermochelys coriacea*), and 1 hawksbill (*Eretmochelys imbricata*) sea turtle to assess temporal change in catch rates, size distributions, sex and genetic ratios, and health of sea turtles. Captures occur annually in coastal waters between Winyah Bay, SC and St. Augustine, FL. Turtles may be handled, blood sampled, measured, flipper and passive integrated transponder (PIT)

tagged, photographed, and released. A subsample of animals are subject to barnacle, keratin, fecal, and tissue sampling, cloacal swabs, and attachment of satellite and/or VHF transmitters. Up to five loggerhead, one Kemp's ridley, one green, one leatherback, and one hawksbill sea turtle could be accidentally killed over the life of the permit. Permit No. 15566–01 increases the number of Kemp's ridleys that may be captured from 29 to 79 turtles annually. The 50 additional sea turtles will be captured, handled, blood sampled, measured, flipper and PIT tagged, photographed, and released.

Issuance of this modification, as required by the ESA, was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of such endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: May 7, 2012.

Tammy C. Adams,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–11522 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA602

Marine Mammals; File Nos. 16109 and 15575

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permits.

SUMMARY: Notice is hereby given that permits have been issued to GeoMarine, Inc. [File No. 16109] (Responsible Party: Jason Holt See; Principal Investigator: Amy Whitt), 2201 K Avenue, Suite A2, Plano, TX 75074 and to Robert A. DiGiovanni Jr. [File No. 15575], Riverhead Foundation for Marine Research and Preservation, 467 East Main St., Riverhead, NY 11901 to conduct research on marine mammals and sea turtles.

ADDRESSES: The permits and related documents are available for review upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376;

Northeast Region, NMFS, 55 Great Republic Drive, Gloucester, MA 01930; phone (978) 281–9328; fax (978) 281–9394; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

FOR FURTHER INFORMATION CONTACT: Joselyd Garcia-Reyes [for File No. 16109] or Laura Morse [for File No. 15575] at (301) 427–8401.

SUPPLEMENTARY INFORMATION: On August 17, 2011, notice was published in the **Federal Register** (76 FR 51001) that requests for permits to conduct research on marine mammals and sea turtles had been submitted by the above-named applicants. The requested permits have been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

File No. 16109: GeoMarine, Inc. was issued a permit that authorizes takes of 35 species of cetaceans, four species of pinnipeds, and five species of sea turtles from New Jersey to North Carolina. The research involves harassment by survey approach during shipboard transect surveys. Eleven of the 44 species targeted for research are listed as threatened or endangered: Blue whale (*Balaenoptera musculus*), fin whale (*B. physalus*), humpback whale (*Megaptera novaeangliae*), North Atlantic right whale (*Eubalaena glacialis*), sei whale (*B. borealis*), sperm whale (*Physeter macrocephalus*), green sea turtle (*Chelonia mydas*), hawksbill sea turtle (*Eretmochelys imbricata*), loggerhead sea turtle (*Caretta caretta*), Kemp's ridley sea turtle (*Lepidochelys kempii*), and leatherback sea turtle (*Dermochelys coriacea*). The permit expires May 15, 2017.

File No. 15575: Robert Di Giovanni, Jr. was issued a permit that authorizes takes of North Atlantic right whales and 43 other marine mammal and sea turtle species to conduct photo-identification surveys from both aerial and vessel platforms from North Carolina to Massachusetts. Eleven of the 44 species to be targeted for research are listed as threatened or endangered: Blue whale, fin whale, humpback whale, North Atlantic right whale, sei whale, sperm whale, green sea turtle, hawksbill sea turtle, loggerhead sea turtle, Kemp's ridley sea turtle, and leatherback sea turtle. In addition, pinniped research includes the placement of remote camera systems at pinniped haul out sites for long-term monitoring of behavior and abundance, and collection of scat for health assessment studies. Opportunistic sighting data will be collected during vessel transits to and from pinniped haul out sites. The permit expires May 15, 2017.

An environmental assessment (EA) was prepared analyzing the effects of the permitted activities on the human environment, in compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Based on the analyses in the EA, NMFS determined that issuance of the permits would not significantly impact the quality of the human environment and that preparation of an environmental impact statement was not required. That determination is documented in a Finding of No Significant Impact (FONSI), signed on May 1, 2012.

As required by the ESA, issuance of these permits was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: May 7, 2012.

Tammy C. Adams,

Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–11521 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Gray's Reef National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applications for the following vacant seats on the Gray's Reef National Marine Sanctuary Advisory Council: sport fishing, conservation and charter/commercial fishing. Applicants are chosen based upon their particular expertise and experience in relation to

the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members should expect to serve 3-year terms, pursuant to the council's Charter.

DATES: Applications are due by June 29, 2012.

ADDRESSES: Application kits may be obtained from Becky Shortland, Council Coordinator (*becky.shortland@noaa.gov,* 10 Ocean Science Circle, Savannah, GA 31411; 912–598–2381). Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Becky Shortland, Council Coordinator (*becky.shortland@noaa.gov,* 10 Ocean Science Circle, Savannah, GA 31411; 912–598–2381).

SUPPLEMENTARY INFORMATION: The sanctuary advisory council was established in August 1999 to provide advice and recommendations on management and protection of the sanctuary. The advisory council, through its members, also serves as liaison to the community regarding sanctuary issues and represents community interests, concerns, and management needs to the sanctuary and NOAA.

Authority: 16 U.S.C. 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: April 27, 2012.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2012–11030 Filed 5–10–12; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA691

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Seismic Survey in Cook Inlet, AK

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of incidental take authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) regulations, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to the Apache Alaska Corporation (Apache) to take marine mammals, by harassment, incidental to a proposed 3D seismic survey in Cook Inlet, Alaska, between April 2012 and April 2013.

DATES: Effective April 30, 2012, to April 30, 2013.

ADDRESSES: A copy of the IHA and application are available by writing to Jolie Harrison, Incidental Take Team Supervisor, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910 or by telephoning the contacts listed here.

A copy of the application used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Brian D. Hopper, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to authorize, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental taking of small numbers of marine mammals shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). The authorization must set forth the permissible methods of taking, other means of effecting the least practicable adverse impact on the specie or stock and its habitat, and requirements pertaining to the mitigation, monitoring and reporting of such takings. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [''Level A harassment'']; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [''Level B harassment''].

Summary of Request

NMFS received an application on June 15, 2011, from Apache for the taking, by harassment, of marine mammals incidental to a 3D seismic survey program in Cook Inlet, Alaska. After addressing comments from NMFS, Apache modified its application and submitted a revised application on July 19, 2011. The July 19, 2011, application was the one available for public comment (see **ADDRESSES**) and considered by NMFS for this IHA. On September 21, 2011, NMFS published a notice in the **Federal Register** (76 FR 58473) discussing the effects on marine mammals and making preliminary determinations regarding a proposed IHA. The notice initiated a 30 day public comment period, which closed on October 21, 2011.

Apache's 3D seismic surveys would employ the use of two source vessels. Each source vessel will be equipped with compressors and 2400 in^3 airgun arrays, as well as additional lower-powered and higher frequency survey equipment for collecting bathymetric and shallow sub-bottom data. In addition, one source vessel will be equipped with a 440 in^3 shallow water airgun array, which it can deploy at high tide in the intertidal area in less than 1.8 m of water. The proposed survey will take place in Cook Inlet.

During the effective period of the IHA, Apache anticipates conducting seismic surveys to cover an ~829 km² (~320 mi²) area along the west coast of Cook Inlet from the McArthur River up and to the south of the Beluga river, in water depths of 0–128 m (0–420 ft). Apache intends to conduct transition zone marine surveys near intertidal areas in water depths of 0–54 m (0–177 ft) beginning in April 2012 and concluding in November 2012. Offshore areas will be surveyed in between April and September 2012 in water depths of 54–128 m (177–420 ft). Apache expects that it will take approximately 160 days—60 days in the nearshore region and 100 days in the offshore region—over the course of 8–9 months to complete the survey. Impacts to marine mammals may occur from noise produced from active acoustic sources (primarily airguns) used in the surveys. There is also an onshore area that will be surveyed; however, this MMPA authorization only addresses takes from in-water activities because a sound source verification (SSV) study conducted in September 2011 indicated that in-water noise levels from explosive detonations onshore will not rise to a level of that would be anticipated to result in harassment of marine mammals in the water.

Description of the Specified Activity

In 2010, Apache acquired over 300,000 acres of oil and gas leases in Cook Inlet with the primary objective to explore for and develop oil fields. In the spring of 2011, Apache conducted a seismic test program to evaluate the feasibility of using new nodal (i.e., no cables) technology seismic recording equipment for operations in the Cook Inlet environment and to test various seismic acquisition parameters to finalize the design for a 3D seismic program in Cook Inlet. The test program took place in late March 2011 and results indicated that the nodal technology was feasible in the Cook Inlet environment. Apache proposes to conduct a phased 3D seismic survey program throughout Cook Inlet over the course of the next three to five years. The first area proposed to be surveyed—and the subject of this IHA—is located along the western coast of mid-Cook Inlet.

The survey operations will be performed from multiple vessels. Apache will employ the use of two source vessels. Each source vessel will be equipped with compressors and 2400 in³ airgun arrays. In addition, one source vessel will be equipped with a 440 in³ shallow water airgun array, which it can deploy at high tide in the intertidal area in less than 1.8 m of water. Three shallow draft vessels will support cable/nodal deployment and retrieval operations, and one mitigation/chase vessel will be used, which will also provide berthing for the Protected Species Observers (PSOs). Finally, two smaller jet boats will be used for personnel transport and node support in the extremely shallow water of the intertidal area. For additional information, such as vessel specifications, see Apache's application.

To cover ~829 km², the survey will take approximately 160 days to complete over the course of 8–9 months. Apache anticipates conducting survey operations 24 hours per day. During each 24 hour period, seismic operations will be active; however, in-water airguns will only be used for approximately 2.5 hours during each of the slack tide periods. There are approximately four slack tide periods in a 24-hour day, therefore, airgun operations will be active during approximately 10–12 hours per day, if weather conditions allow.

NMFS outlined the purpose of the program in a previous notice for the proposed IHA (76 FR 58473, September 21, 2011). The activities to be conducted have not changed between the proposed IHA notice and this final notice announcing the issuance of the IHA. For a more detailed description of the activity, including vessel and acoustic source specifications, the reader should refer to the proposed IHA notice (76 FR 58473, September 21, 2011), the IHA application and associated documents referenced above this section.

Comments and Responses

A notice of receipt of the Apache application and proposed IHA was published in the **Federal Register** on September 21, 2011 (76 FR 58473). During the 30-day public comment period, NMFS received comments from the Marine Mammal Commission (Commission), the Alaska Department of Fish and Game, environmental non-governmental organizations (NGOs), and one member of the public. Following are their comments and NMFS's responses:

Comment 1: The Commission recommended that NMFS require the applicant to re-estimate the ensonified areas for each sound threshold (i.e., 190, 180, and 160 dB re 1 μPa) and the expected number of marine mammal takes, accounting for simultaneous, alternating use of two sound sources and the overlap of their acoustic footprints.

Response: The two source vessels will survey the area using a ''ping/pong'' technique. This method does not require the two vessels to fire their airgun arrays simultaneously. Instead, the first vessel fires the initial shot and then the second vessel fires its array about 12 seconds later. The first vessel would then fire its second shot 12 seconds after the second vessel has fired its airguns and so on. No other sources will be active at the same time as the airgun arrays because any additional sources may compromise the collection of seismic data from the airguns. As described in Section 6.2 of the IHA application, acoustic impacts were calculated based on the largest sound source, the 2400 in³ array, and included the ping/pong survey method described above. The calculations were performed for a 24-hour period of seismic survey activity. The estimated takes predicted with the 24-hour calculations factored in the 24-hour acoustic footprint, the estimated number of days surveyed in the respective depths, and the estimated marine mammal abundances.

Comment 2: The Commission recommended that NMFS require the applicant to describe and provide the rationale for the method used to determine the density estimate for beluga whales away from river mouths and recalculate the density estimates accordingly.

Response: The abundance estimate for belugas was derived from the highest daily mean count acquired during the annual surveys (i.e., the highest number of individuals observed in the area over the entire survey period). As noted in Section 6.3 of the IHA application, belugas are found in much higher concentrations in river mouths (e.g., Chickaloon Bay and Susitna Delta) compared to other areas. The applicant used the average number of belugas for the non-river mouths as a conservative estimate; however, in response to the Commission's recommendation, Apache has removed the Chickaloon Bay and Susitna Delta highest daily mean counts and re-calculated the maximum number of belugas observed, which results in higher abundance estimates for non-river mouths. The revised average density is 0.00012 with a maximum of 0.00037 for non-river mouths.

Comment 3: The Commission recommended that NMFS require the applicant to recalculate the estimated number of takes for all species based on the modeled areas of ensonification for each sound threshold (i.e., 190, 180, and 160 dB re μ1 Pa), using the full number of survey days rather than half that number.

Response: The acoustic footprints were calculated on a 24-hour basis, but surveys will only take place 12 hours per day; therefore, authorization for

marine mammal takes incidental to the seismic survey will only be necessary during 12 hours per day when surveys are conducted. In-water airguns will only be active for approximately 2.5 hours during periods of slack tide. There are approximately 4 slack tide periods every 24 hours; therefore, airguns will be active approximately 10–12 hours per day, if weather conditions allow. Apache anticipates that a crew can acquire approximately 5.2 km^2 per day, assuming an efficient crew can work 10–12 hours per day.

Comment 4: The Commission recommended that NMFS require the applicant to either amend its application to seek authorization to take the full number of marine mammals that may be taken or provide sufficient justification for requesting lesser numbers of takes, particularly for beluga whales and harbor seals.

Response: The application and NMFS' IHA authorize take for the total taking estimated. Estimating take begins with a mathematical formula, but may be adjusted upward or downward to account for factors such as effects of mitigation and monitoring and species group size. See the section in this **Federal Register** notice titled Estimated Take by Incidental Harassment, which has been updated for increased clarity, for an explanation of how take estimates were calculated for this activity.

Comment 5: The Commission recommended that NMFS ensure that the monitoring measures included in the authorization are sufficient to account for all takes of marine mammals and require the applicant to provide timely reports of the number of marine mammals taken so that surveys can be stopped before the authorized takes are exceeded.

Response: For this project, the required marine mammal monitoring serves two primary purposes. One purpose is to trigger mitigation measures—so when a marine mammal is sighted within or entering the identified 180 or 190 dB exclusion zones, appropriate measures are taken to minimize the likelihood that marine mammals are exposed to injurious sound levels; and under certain circumstances, mitigation action will be taken when marine mammals are sighted within or approaching the 160 dB zone. The second purpose is to collect data regarding the behavior and numbers of marine mammals detected within the 160 dB zone, which can be used to refine Level B harassment take estimates and contributes to our understanding of the nature and scale of marine mammals behavioral responses to seismic surveys. To better account for marine mammal takes that occur during the survey and ensure that takes do not exceed the amount authorized in the IHA, NMFS has included an additional reporting requirement in the IHA that will require the applicant to submit weekly and monthly reports to the Permits and Conservation Division. These reports will contain information regarding the species detected, in-water activity occurring at the time of the sighting, behavioral reactions to in-water activities, and the number of marine mammals taken. NMFS believes that the inclusion of a weekly and monthly reporting requirement will allow both NMFS and Apache to regularly track the number and nature of marine mammal takes, and ensure that takes do not exceed what is authorized by the IHA. In addition, following the completion of the survey, Apache will submit a draft report on all activities and monitoring results to the Office of Protected Resources within 90 days of the completion of the Apache survey.

Comment 6: Environmental NGOs commented that NMFS should not rely on its regulatory definition of ''small numbers'' that was found to be improper by a U.S. District Court in *Natural Resources Defense Council* v. *Evans, 279 F.Supp. 2d 1129 (N.D. Ca. 2003).* They also commented that the take of 30 Cook Inlet beluga whales is not a ''small number'' for such an isolated, endangered population.

Response: NMFS does not rely on the 1982 regulatory definition of small numbers for its incidental take authorizations. Instead, NMFS addresses ''small numbers'' in terms relative to the stock or population size. Apache requested, and NMFS authorizes, the take of 30 Cook Inlet beluga whales by Level B harassment, which represents about 10 percent of the population if one assumes that each take is a separate individual animal. In addition, the percentage would be even lower if animals make minor course adjustments to avoid the approaching seismic survey area in a manner that does not result in take at all. Additionally, the requirement to cease operating when cow-calf pairs or groups of 5 or more animals enter the 160dB zone is likely to further reduce the number of individuals taken. NMFS has determined that the small numbers requirement has been satisfied for this IHA. The status of the Cook Inlet beluga population (i.e., the fact that it is an isolated, endangered population) has been carefully considered in NMFS' negligible impact analysis.

Comment 7: Environmental NGOs commented that NMFS's assumption that marine mammals will not be harassed by sounds below 160 dB re 1 μPa (rms) is arbitrary and not supported by science. The NGOs support their comment by providing as an example the sensitivity of harbor porpoises to noise and NMFS's use of 120 dB as a threshold when authorizing take incidental to Navy sonar activities. In addition, the commenters refer to a recent decision document related to seismic surveys in the Chukchi Sea where NMFS imposed a 120 dB safety zone for aggregations of bowhead whales.

Response: NMFS does not agree with the commenter's assessment of the 160 dB threshold. NMFS uses 160 dB for most species in most cases based on the best available information. NMFS established the current Level B harassment (sub-injurious) thresholds for underwater sound sources (except explosives and tactical active sonar) based on measured avoidance responses observed in whales in the wild. Specifically, the 160 dB threshold was derived from data for mother-calf pairs of migrating gray whales (Malme *et al.,* 1983, 1984) and bowhead whales (Richardson *et al.,* 1985, 1986) responding to seismic airguns (e.g., impulsive sound source). This threshold has been applied to a variety of activities, such as seismic surveys and impact pile driving.

Regarding the 120 dB threshold for the onset of behavioral harassment for harbor porpoises by Navy sonar activities, that threshold is limited to exposure to mid- and high-frequency sonar signals, which are defined as sound with dominant frequency at 1–10 kHz and above 10 kHz, respectively. In contrast, sounds produced during marine seismic surveys have most of their energy concentrated at the lower end of the frequency spectrum, which is largely outside of the frequency range where harbor porpoises have the highest sensitivity (Anderson 1970; Kastelein *et al.* 2002). Harbor porpoises are considered sensitive species that respond to active sonar signals at lower received levels than other species in a manner that NMFS considers Level B harassment. Therefore, NMFS believes that it is scientifically justifiable to use received level at 120 dB as the threshold for behavioral harassment for harbor porpoises exposed to mid- and high-frequency Navy sonar, but it is not appropriate to use this received level as the threshold for behavioral harassment for harbor porpoises or other marine mammal species when exposed to sounds from seismic surveys. NMFS continues to believe that the 160 dB threshold is appropriate for determining the level of take of marine mammals by

Level B harassment for impulse noise (such as from airguns).

Separately, the comment about mitigation measures for aggregations of bowheads is incorrect. NMFS has included shutdown measures at the *160* dB threshold for aggregations of bowheads in the Arctic during seismic surveys, but not 120 dB. Moreover, this measure was required to ensure no unmitigable adverse impact on the availability of bowheads for subsistence uses, pursuant to the MMPA, not strictly as a means to effect the least practicable impact on bowhead whales. Bowhead whales, hunted by Alaska Natives, are low-frequency hearing specialists (unlike any of the species in Cook Inlet) and the frequency of seismic airguns falls within the frequency range of their highest sensitivity. During migration, they may respond to received levels below 160 dB in a manner that could potentially interfere with a subsistence hunt (e.g., causing a minor deflection in their migratory path), but which NMFS would not consider harassment. In addition, these minor course changes occurred during migration and have not been seen at other times of the year and during other activities.

Comment 8: Environmental NGOs commented that because the status of Cook Inlet beluga whales is so tenuous, NMFS cannot conclude that the activities that will harass a significant portion of the population will have no more than a negligible effect on the stock.

Response: NMFS took into account the status of Cook Inlet beluga whales as well as other factors in making its negligible impact determination, as explained in this **Federal Register** Notice. NMFS used the best scientific information to support the analyses for its preliminary determination in its proposed IHA notice (76 FR 58473, September 21, 2011) and its final determination presented in this **Federal Register** notice.

Comment 9: Environmental NGOs commented that NMFS cannot make a negligible impact finding because the agency has failed to address the likely impact of a large scale stranding event caused by Apache's activities.

Response: Marine mammals close to underwater detonations of high explosive can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.* 1993; Ketten 1995). Air gun pulses are less energetic and their peak amplitudes have slower rise times. To date, there is no evidence that serious injury, death, or stranding by marine mammals can occur from exposure to airgun pulses, even in the case of large airgun arrays.

However, in numerous past IHA notices for seismic surveys, commenters have referenced two stranding events allegedly associated with seismic activities, one off Baja California and a second off Brazil. NMFS has addressed this concern several times, and, without new information, does not believe that this issue warrants further discussion. For information relevant to strandings of marine mammals, readers are encouraged to review NMFS' response to comments on this matter found in 69 FR 74905 (December 14, 2004), 71 FR 43112 (July 31, 2006), 71 FR 50027 (August 24, 2006), and 71 FR 49418 (August 23, 2006). In addition, a May–June 2008, stranding of 100–200 melon-headed whales (*Peponocephala electra*) off Madagascar that appears to be associated with seismic surveys is currently under investigation (IWC 2009).

It should be noted that strandings related to sound exposure have not been recorded for marine mammal species in Cook Inlet. NMFS notes that beluga whale strandings in Cook Inlet are not uncommon; however, these events often coincide with extreme tidal fluctuations (''spring tides'') or killer whale sightings (Shelden *et al.,* 2003). No strandings or marine mammals in distress were observed during the 2D test survey conducted by Apache in March 2011, and none were reported by Cook Inlet inhabitants. As a result, NMFS does not expect any marine mammals will incur serious injury or mortality in Cook Inlet or strand as a result of the proposed seismic survey.

Comment 10: Environmental NGOs commented that the MMPA's negligible impact standard requires NMFS to consider the effects of the proposed seismic activities on Cook Inlet beluga whales together with all other activities that affect belugas in Cook Inlet and not issuing an Environmental Assessment (EA) or Environmental Impact Statement (EIS) in advance of proposing to issue an IHA makes it impossible for the public to know whether cumulative effects have been properly considered.

Response: Section 101(a)(5)(D) of the MMPA requires NMFS to make a determination that the harassment incidental to a specified activity will have a negligible impact on the affected species or stocks of marine mammals, and will not result in an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. Neither the MMPA nor NMFS' implementing regulations specify how to consider other activities and their impacts on the same populations. However, consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into the negligible impact analysis via their impacts on the environmental baseline (e.g., as reflected in the density/distribution and status of the species, population size and growth rate, and ambient noise).

In addition, cumulative effects were addressed in the Environmental Assessment and biological opinion prepared for this action, both of which NMFS indicated would be completed prior to the issuance of an IHA (76 FR 58473). These documents, as well as the Alaska Marine Stock Assessments and the most recent abundance estimate for Cook Inlet beluga whales (Hobbs *et al.* 2011), are part of NMFS' Administrative Record for this action, and provided the decision maker with information regarding other activities in the action area that affect marine mammals, an analysis of cumulative impacts, and other information relevant to the determination made under the MMPA.

Comment 11: Environmental NGOs commented that given the very low subsistence take of Cook Inlet beluga whales in recent years, the injury or mortality of a single beluga by Apache's activities could preclude any subsistence harvest; therefore, NMFS cannot conclude that the incidental take does not have ''an unmitigable adverse impact on the availability of such species or stock for taking for subsistence uses'' by Alaska Natives.

Response: Unmitigable adverse impact means an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammal to abandon or avoid hunting areas; (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met. Currently there is no subsistence hunting of Cook Inlet belugas authorized (73 FR 60976, October 15, 2008). Apache did not request and NMFS does not anticipate, nor is it authorizing, any Level A harassment takes of Cook Inlet beluga whales or takes by mortality incidental to the seismic surveys. The required mitigation and monitoring measures are designed to avoid exposing any marine mammals, including Cook Inlet beluga

whales, to sound levels that may result in injury; therefore, NMFS believes that any adverse impact from the specified activity can be mitigated. For example, protected species observers will monitor the marine mammal exclusion zone while a sound source is active and have the authority to require power-downs or shut-downs to ensure that Level A harassment takes do not occur. In the unlikely event that marine mammals do get exposed to injurious levels of sound, the IHA will require Apache to cease work and report the incident to NMFS.

Comment 12: Environmental NGOs commented that NMFS should reconsider allowing Apache to continue seismic surveys during nighttime (low light) and other low visibility conditions.

Response: Section 101(a)(5)(D) of the MMPA requires NMFS to prescribe means of effecting the least practicable impact on marine mammal species or stocks. With respect to Apache's seismic survey, (1) marine mammals would need to be within about 330 m of the 10 cubic inch ''mitigation'' airgun to be exposed to the 160 dB and within about 33 m to be exposed to injurious levels of sound; (2) the approaching airgun arrays, source vessels, and support vessels preclude or discourage marine mammals from entering the action area by alerting animals to the presence of the activity; and (3) the continuous operation of the mitigation airgun at night if survey shooting is to occur at night will alert marine mammals to the presence of survey vessels in the area, which allows them the opportunity to move away before being exposed to injurious levels of sound.

With respect to practicability, NMFS believes that requiring Apache to halt seismic surveys during nighttime and other low visibility conditions would increase the amount of time it would take Apache to complete the survey and may require additional survey vessels to be brought into Cook Inlet. As a result, NMFS considers the implementation of this recommendation as a mitigation measure to be impracticable for both economic and practical reasons.

However, to further enhance the detection of marine mammals, passive acoustic monitoring (PAM) systems will be deployed, if ice conditions allow, inside the 180/190 dB safety zone in both the up-inlet and down-inlet directions. The fixed system will include two JASCO Advanced Multichannel Acoustic Recorders that send real-time acoustic data via digital UHF radio-broadcast systems to PAM operators aboard the M/V *Dreamcatcher.* If ice is present, the PAM system can be deployed from the vessel. The PAM operators use specialized real-time detection software and audio playback to detect marine mammal sounds. If PAM operators detect a marine mammal vocalizing, they are authorized to instruct Apache to initiate a shut-down or power-down of airguns. If a shut-down occurs at night, seismic surveys will be suspended until the following day and the full safety zone is visible.

Moreover, as stated in the **Federal Register** notice proposing the IHA, at night, the vessel captains and crews will maintain lookout for marine mammals and will order the airgun(s) to be shut down if marine mammals are observed in or about to enter the safety radii. As with shut-down initiated by acoustic detection of marine mammals at night, if a shut down occurs, survey activities will be suspended until the following day and will only be resumed if the full safety zone is visible. At that point, the ramp-up requirement for airguns and other seismic equipment during normal visual conditions is expected to keep marine mammals from entering the established safety zones.

Comment 13: Environmental NGOs commented that NMFS must examine the practicability of including additional mitigation measures, such as time/area restrictions on the proposed activities, based on marine mammal activity and habitat use.

Response: NMFS considered including time/area restrictions. Beluga whales remain in Cook Inlet year-round, but demonstrate seasonal movement within the Inlet; in the summer and fall, they concentrate in upper Cook Inlet's rivers and bays, but tend to disperse offshore and move to mid-Inlet in winter (Hobbs *et al.,* 2005). The available information indicates that in the winter months belugas concentrate in deeper waters in mid-Inlet past Kalgin Island, with occasional forays into the upper inlet, including the upper ends of Knik and Turnagain Arms. Their winter distribution does not appear to be associated with river mouths, as it is during the warmer months. The spatial dispersal and diversity of winter prey are likely to influence the wider beluga winter range throughout the mid-Inlet. Apache now expects to commence its seismic survey in April, which would coincide with the time of year when belugas are dispersed offshore in the mid-Inlet and away from river mouths. In the spring, beluga whales are regularly sighted in the upper Inlet beginning in late April or early May, coinciding with eulachon runs in the Susitna River and Twenty Mile River in Turnagain Arm, and well outside of the area where Apache will be conducting seismic surveys. Therefore, NMFS believes that the timing and location of the seismic survey, as proposed, will avoid areas and seasons that overlap with important beluga whale behavioral patterns.

Comment 14: Environmental NGOs commented that NMFS must resubmit the proposed IHA for notice and comment when the results from the sound source verification study assessing underwater noise produced on explosive detonations onshore become available.

Response: In the **Federal Register** notice announcing the proposed IHA, NMFS indicated that Apache would be conducting a sound source verification (SSV) study to measure in-water noise from the detonation of explosives onshore (76 FR 58473, September 21, 2011). The results from this study are summarized below and the complete report is posted on the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* On September 17–18, 2011, two acoustic teams conducted the SSV test to ensure that marine mammals would not be exposed to underwater received levels exceeding NMFS' threshold for Level B harassment during the proposed seismic survey. The SSV test consisted of a total of seven shot locations beginning in the mudflats, three locations in the lowlands and spaced every half mile for 4 miles inland, for a total of 24 holes. Each location had a 1 kg charge buried at 25 ft, a 2 kg charge buried at 25 ft, and a 4 kg charge buried at 35 ft. To monitor the explosions onshore, three JASCO Ocean Bottom Hydrophones (OBHs) were deployed at 3 km, 6 km, and 10 km from the last shothole on the testline two JASCO vessel-based real-time acoustic monitoring and data logging stations were deployed from vessels located at 3 km and 6 km from the last shothole on the testline, and one 4-channel particle velocity and acceleration measurement system was deployed from a vessel approximately 1 km from the last shothole on the testline. The results were analyzed from the three loudest shots recorded on the OBH and vessel-based data logging systems located 3 km from the shot nearest the vessels. The OBH was at a depth of approximately 30 m, 1.5 m above the seafloor, and the over-the-side system was at a depth of 2 m. In general, the sound levels measured by the over-the-side hydrophone were lower than those measured by the OBH; however, this was expected because low-frequency sounds are strongly attenuated near the sea surface due to the proximity of the pressure-release boundary. The OBH at 3 km recorded

received levels between 142–144 dB re 1 μPa (0–Peak SPL) and between 130–132 dB re 1 μPa²/s SEL. The over-the-side system at 3 km recorded received levels of between 117–124 dB re 1 μPa (0–Peak SPL) and between 106–114 dB re 1 μPa²/s SEL. These results are well below the NMFS criterion of 160 dB and do not constitute an activity that would result in the incidental take of marine mammals or require inclusion in Apache's IHA request.

Description of Marine Mammals in the Area of the Specified Activity

The marine mammal species under NMFS's jurisdiction that could occur near operations in Cook Inlet include three cetacean species: beluga whale (*Delphinapterus leucas*), killer whale (*Orcinus orca*), and harbor porpoise (*Phocoena phocoena*), and two pinniped species: harbor seal (*Phoca vitulina richardsi*) and Steller sea lions (*Eumetopias jubatus*). The marine mammal species that is likely to be encountered most widely (in space and time) throughout the period of the planned survey is the harbor seal.

Of the five marine mammal species likely to occur in the proposed marine survey area, only Cook Inlet beluga whales and Steller sea lions are listed as endangered under the ESA (Steller sea lions are listed as two distinct population segments (DPSs), an eastern and a western DPS; the relevant DPS in Cook Inlet is the western DPS). These species are also designated as ''depleted'' under the MMPA. Despite these designations, Cook Inlet beluga whales and the western DPS of Steller sea lions have not made significant progress towards recovery. The Cook Inlet population of beluga whales has been decreasing at a rate of 1.5 percent annually for nearly a decade (Allen and Angliss, 2010). With respect to Steller sea lions, results of aerial surveys conducted in 2008 (Fritz *et al.,* 2008) confirmed that the recent (2004–2008) overall trend in the western population of adult and juvenile Steller sea lions in Alaska is stable or possibly in decline; however, there continues to be considerable regional variability in recent trends. Pursuant to the ESA, critical habitat has been designated for Cook Inlet beluga whales and Steller sea lions. The proposed action falls within critical habitat designated in Cook Inlet for beluga whales, but is not within critical habitat designated for Steller sea lions. The portion of beluga whale critical habitat—identified as Area 2—where the seismic survey will occur is located south of the Area 1 critical habitat where belugas are particularly vulnerable to impacts due to their high seasonal densities and the biological importance of the area for foraging, nursery, and predator avoidance. Area 2 is largely based on dispersed fall and winter feeding and transit areas in waters where whales typically appear in smaller densities or deeper waters (76 FR 20180, April 11, 2011).

Cetaceans

Beluga Whales—Cook Inlet beluga whales reside in Cook Inlet year-round although their distribution and density change seasonally. Factors that are likely to influence beluga whale distribution within the inlet include prey availability, predation pressure, sea-ice cover, and other environmental factors, reproduction, sex and age class, and human activities (Rugh *et al.,* 2000; NMFS, 2008). Seasonal movement and density patterns as well as site fidelity appear to be closely linked to prey availability, coinciding with seasonal salmon and eulachon concentrations (Moore *et al.,* 2000). For example, during spring and summer, beluga whales are generally concentrated near the warmer waters of river mouths where prey availability is high and predator occurrence is low (Huntington 2000; Moore *et al.,* 2000). Beluga whales use several areas of the upper Cook Inlet for repeated summer and fall feeding. The primary hotspots for beluga feeding include the Big and Little Susitna rivers, Eagle Bay to Eklutna River, Ivan Slough, Theodore River, Lewis River, and Chickaloon River and Bay (NMFS, 2008). Availability of prey species appears to be the most influential environmental variable affecting Cook Inlet beluga whale distribution and relative abundance (Moore *et al.,* 2000). The patterns and timing of eulachon and salmon runs have a strong influence on beluga whale feeding behavior and their seasonal movements (Nemeth *et al.,* 2007; NMFS 2008). The presence of prey species may account for the seasonal changes in beluga group size and composition (Moore *et al.,* 2000).

Aerial and vessel-based monitoring conducted by Apache during the March 2011 2D test program in Cook Inlet reported 33 beluga sightings. One of the sightings was of a large group (~25 individuals on March 27, 2011) of feeding/milling belugas near the mouth of the Drift River. Also on March 27, 2011, PSOs onboard the M/V *Dreamcatcher* reported a group of seven beluga whales approximately 0.5 nm from the vessel. Land-based PSOs were able to observe this group of beluga whales for approximately 2.5 hrs. A single beluga whale was observed near the mouth of the Drift River by the aerial-based monitors on March 28, 2011, prior to the seismic ramp-up period. If belugas are present during the late summer/early fall, they are more likely to occur in shallow areas near river mouths in upper Cook Inlet. As explained below in the section on Estimated Takes, expected densities were calculated from the annual aerial surveys conducted by NMFS between 2000 and 2010 (Rugh *et al.,* 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007; Shelden *et al.,* 2008, 2009, 2010). In response to the Commission's recommendation (see Comment #2), Apache recalculated beluga whale densities for non-river mouths. Those updated densities are presented in Table 3.

Killer Whales—In general, killer whales are rare in upper Cook Inlet, where transient killer whales are known to feed on beluga whales and resident killer whales are known to feed on anadromous fish (Shelden *et al.,* 2003). The availability of these prey species largely determines the likeliest times for killer whales to be in the area. Between 1993 and 2004, 23 sightings of killer whales were reported in the lower Cook Inlet during aerial surveys by Rugh *et al.* (2005). Surveys conducted over a span of 20 years by Shelden *et al.* (2003) reported 11 sightings in upper Cook Inlet between Turnagain Arm, Susitna Flats, and Knik Arm. No killer whales were spotted during recent surveys by Funk *et al.* (2005), Ireland *et al.* (2005), Brueggeman *et al.* (2007a, 2007b, 2008), or Prevel Ramos *et al.* (2006, 2008). Eleven killer whale strandings have been reported in Turnagain Arm, six in May 1991 and five in August 1993. Therefore, few killer whales, if any, are expected to approach or be in the vicinity of the action area.

Harbor Porpoise—The most recent estimated maximum density for harbor porpoises in Cook Inlet is 7.2 per 1,000 km² (Dahlheim *et al.,* 2000) indicating that only a small number use Cook Inlet. Harbor porpoise have been reported in lower Cook Inlet from Cape Douglas to the West Foreland, Kachemak Bay, and offshore (Rugh *et al.,* 2005). Small numbers of harbor porpoises have been consistently reported in upper Cook Inlet between April and October, except for a recent survey that recorded higher than usual numbers. Prevel Ramos *et al.* (2008) reported 17 harbor porpoises from spring to fall 2006, while other studies reported 14 in the spring of 2007 (Brueggeman *et al.,* 2007) and 12 in the fall (Brueggeman *et al.,* 2008). During the spring and fall of 2007, 129 harbor porpoises were reported between Granite Point and the Susitna River; however, the reason for the higher numbers of harbor porpoise in the upper Cook Inlet remains unclear and the

disparity with the results of past sightings suggests that it may be an anomaly. The spike in reported sightings occurred in July, which was followed by sightings of 79 harbor porpoises in August, 78 in September, and 59 in October, 2007. It is important to note that the number of porpoises counted more than once was unknown, which suggests that the actual numbers are likely smaller than those reported. On the other hand, recent passive acoustic research in Cook Inlet by the Alaska Department of Fish and Game and the National Marine Mammal Laboratory have indicated that harbor porpoises occur in the area more frequently than previously thought, particularly in the West Foreland area in the spring (NMFS 2011); however overall numbers are still unknown at this time.

Pinnipeds

Harbor Seals—Harbor seals inhabit the coastal and estuarine waters of Cook Inlet. In general, harbor seals are more abundant in lower Cook Inlet than in upper Cook Inlet, but they do occur in the upper inlet throughout most of the year (Rugh *et al.,* 2005). Harbor seals are non-migratory; their movements are associated with tides, weather, season, food availability, and reproduction. The major haulout sites for harbor seals are located in lower Cook Inlet and their presence in the upper inlet coincides with seasonal runs of prey species. For example, harbor seals are commonly observed along the Susitna River and other tributaries along upper Cook Inlet during the eulachon and salmon migrations (NMFS, 2003). During aerial surveys of upper Cook Inlet in 2001, 2002, and 2003, harbor seals were observed 24 to 96 km south-southwest of Anchorage at the Chickaloon, Little Susitna, Susitna, Ivan, McArthur, and Beluga Rivers (Rugh *et al.,* 2005). During the 2D test program in March 2011, two harbor seals were observed by vessel-based PSOs. On March 25, 2011, one harbor seal was observed approximately 400 m from the M/V *Miss Diane.* At the time of the observation, the vessel was operating the positioning pinger and PSOs instructed the operator to implement a shut-down. The pinger was shut down for 30 minutes while PSO monitored the area and re-started the device when the animal was not sighted again during the 30 minute site clearing protocol. No unusual behaviors were reported during the time the animal was observed. The second harbor seal was observed on March 26, 2011, by vessel-based PSO onboard the M/V *Dreamcatcher* approximately 4260 m from the source vessel, which was operating the 10 in^3 airgun at the time. The animal was well outside of the 160 dB zone (330 m for the 10 in^3 airgun) and no unusual behaviors were observed. The closest haulout site to the action area is located on Kalgin Island, which is approximately 22 km away from the McArthur River.

Steller Sea Lion—Two separate stocks of Steller sea lions are recognized within U.S. waters: an eastern DPS, which includes animals east of Cape Suckling, Alaska; and a western DPS, which includes animals west of Cape Suckling (NMFS, 2008). Individuals in Cook Inlet are considered part of the western DPS, which is listed as endangered under the ESA. Steller sea lions primarily occur in lower, rather than upper Cook Inlet and are rarely sighted north of Nikiski on the Kenai Peninsula. Haul-outs and rookeries are located near Cook Inlet at Gore Point, Elizabeth Island, Perl Island, and Chugach Island (NMFS, 2008). No Steller seal lion haul-outs or rookeries are located in the vicinity of the proposed seismic survey. Furthermore, no sightings of Steller sea lions were reported by Apache during the 2D test program in March 2011. Although Apache has requested takes of Steller sea lions, it is unlikely that any Steller sea lions would occur in the action area during seismic survey operations.

Apache's application contains additional information on the status, distribution, seasonal distribution, and abundance of each of the affected species under NMFS' jurisdiction mentioned in this document. Please refer to the application for that information (see **ADDRESSES**). Additional information can also be found in the NMFS Stock Assessment Reports (SAR). The Alaska 2010 SAR is available at: *http://www.nmfs.noaa.gov/pr/pdfs/sars/ak2010.pdf.*

Potential Effects of the Airgun Sounds on Marine Mammals

The effects of sounds from airgun pulses might include one or more of the following: tolerance, masking of natural sounds, behavioral disturbance, temporary or permanent hearing impairment, or non-auditory physical or physiological effects (Richardson *et al.,* 1995; Gordon *et al.,* 2004; Nowacek *et al.,* 2007; Southall *et al.,* 2007). As outlined in previous NMFS documents, the effects of noise on marine mammals are highly variable. The Notice of Proposed IHA (76 FR 58473, September 21, 2011) included a discussion of the effects of airguns on marine mammals, which is not repeated here. That discussion took into consideration the monitoring and mitigation measure proposed by Apache and NMFS. No cases of temporary threshold shift (TTS) are expected as a result of Apache's activities given the small size of the source, the strong likelihood that marine mammals would avoid the approaching airguns (or vessels) before being exposed to levels high enough for there to be any possibility of TTS, and the mitigation measures required to be implemented during the survey described later in this document. Based on the fact that the sounds produced by Apache's operations are unlikely to cause TTS in marine mammals, it is extremely unlikely that permanent hearing impairment would result. No injuries or mortalities are anticipated as a result of Apache's operations, and none are authorized to occur. Only Level B harassment is anticipated as a result of Apache's activities.

Potential Effects From Pingers on Marine Mammals

Active acoustic sources other than the airguns have been proposed for Apache's 2012 seismic survey in Cook Inlet. The specifications for the pingers (source levels and frequency ranges) were provided in the Notice of Proposed IHA (76 FR 58473, September 21, 2011). In general, the potential effects of this equipment on marine mammals are similar to those from the airguns, except the magnitude of the impacts is expected to be much less due to the lower intensity of the source.

Potential Effects From Vessels and Vessel Noise on Marine Mammals

Vessel activity and noise associated with vessel activity will temporarily increase in the action area during Apache's seismic survey as a result of the operation of eight vessels. To minimize the effects of vessels and noise associated with vessel activity, Apache will follow NMFS' Marine Mammal Viewing Guidelines and Regulations and will alter heading or speed if a marine mammal gets too close to a vessel. In addition, vessels will be operating at slow speed (2–4 knots) when conducting surveys and in a purposeful manner to and from work sites in as direct a route as possible. Marine mammal monitoring observers and passive acoustic devices will alert vessel captains as animals are detected to ensure safe and effective measures are applied to avoid coming into direct contact with marine mammals. Therefore, NMFS neither anticipates nor authorizes takes of marine mammals from ship strikes.

Odontocetes, such as beluga whales, killer whales, and harbor porpoises, often show tolerance to vessel activity;

however, they may react at long distances if they are confined by ice, shallow water, or were previously harassed by vessels (Richardson, 1995). Beluga whale response to vessel noise varies greatly from tolerance to extreme sensitivity depending on the activity of the whale and previous experience with vessels (Richardson, 1995). Reactions to vessels depends on whale activities and experience, habitat, boat type, and boat behavior (Richardson, 1995) and may include behavioral responses, such as altered headings or avoidance (Blane and Jaakson, 1994; Erbe and Farmer, 2000); fast swimming; changes in vocalizations (Lesage *et al.,* 1999; Scheifele *et al.,* 2005); and changes in dive, surfacing, and respiration patterns.

There are few data published on pinniped responses to vessel activity, and most of the information is anecdotal (Richardson, 1995). Generally, sea lions in water show tolerance to close and frequently approaching vessels and sometimes show interest in fishing vessels. They are less tolerant when hauled out on land; however, they rarely react unless the vessel approaches within 100–200 m (330–660 ft; reviewed in Richardson, 1995).

The addition of eight vessels and noise due to vessel operations associated with the seismic survey would not be outside the present experience of marine mammals in Cook Inlet, although levels may increase locally. Given the large number of vessels in Cook Inlet and the apparent habituation to vessels by Cook Inlet beluga whales and the other marine mammals that may occur in the area, vessel activity and noise is not expected to have effects that could cause significant or long-term consequences for individual marine mammals or their populations.

Potential Effects From Aircraft Noise on Marine Mammals

Apache plans to utilize the crew helicopter to conduct aerial surveys near river mouths in order to identify locations or congregations of beluga whales and other marine mammals prior to the commencement of operations. The helicopter will not be used every day, but will be used for surveys near river mouths. Aerial surveys will fly at an altitude of 305 m (1,000 ft) when practicable and weather conditions permit. In the event of a marine mammal sighting, aircraft will try to maintain a radial distance of 457 m (1,500 ft) from the marine mammal(s). Aircraft will avoid approaching marine mammals from head-on, flying over or passing the shadow of the aircraft over the marine mammals.

Studies on the reactions of cetaceans to aircraft show little negative response (Richardson *et al.,* 1995). In general, reactions range from sudden dives and turns and are typically found to decrease if the animals are engaged in feeding or social behavior. Whales with calves or in confined waters may show more of a response. Generally there has been little or no evidence of marine mammals responding to aircraft overflights when altitudes are at or above 1,000 ft, based on three decades of flying experience in the Arctic (NMFS, unpublished data). Based on long-term studies that have been conducted on beluga whales in Cook Inlet since 1993, NMFS expect that there will be no effects of this activity on beluga whales or other cetaceans. No change in beluga swim directions or other noticeable reactions have been observed during the Cook Inlet aerial surveys flown from 600 to 800 ft. (e.g., Rugh *et al.,* 2000). By applying the operational requirements discussed above, sound levels underwater are not expected to reach NMFS' harassment thresholds.

The majority of observations of pinnipeds reacting to aircraft noise are associated with animals hauled out on land or ice. There are very little data describing the reactions of pinnipeds in water to aircraft (Richardson *et al.,* 1995). In the presence of aircraft, pinnipeds hauled out for pupping or molting generally became alert and then rushed or slipped (when on ice) into the water. Stampedes often result from this response and may increase pup mortality due to crushing or an increased rate of pup abandonment. The greatest reactions from hauled out pinnipeds were observed when low flying aircraft passed directly above the animal(s) (Richardson *et al.,* 1995). Although noise associated with aircraft activity could cause hauled out pinnipeds to rush into the water, there are no known haul out sites in the vicinity of the survey site.

Therefore, the operation of aircraft during the seismic survey is not expected to have effects that could cause significant or long-term consequences for individual marine mammals or their populations. To minimize the noise generated by aircraft, Apache will follow NMFS' Marine Mammal Viewing Guidelines and Regulations found at *http://www.alaskafisheries.noaa.gov/protectedresources/mmv/guide.htm.*

Anticipated Effects on Marine Mammal Habitat

NMFS included a detailed discussion of the potential effects of this action on marine mammal habitat, including physiological and behavioral effects on marine fish and invertebrates, in the notice of the proposed IHA (76 FR 58473, September 21, 2011). While NMFS anticipates that the specified activity may result in marine mammals avoiding certain areas due to temporary ensonification, this impact to habitat is temporary and site-specific, which NMFS considered as behavioral modification. The main impact associated with the activity would be temporarily elevated noise levels and the associated direct effects on marine mammals.

Mitigation

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

To reduce the potential for disturbance from acoustic stimuli associated with the activities, Apache and/or its designees will implement the following mitigation measures for marine mammals:

(1) Operation of Mitigation Airgun at Night

Apache proposes to conduct both daytime and nighttime operations. Nighttime operations will only be initiated if a mitigation airgun (typically the 10 in^3) has been continuously operational from the time that PSO monitoring has ceased for the day. The mitigation airgun will operate on a longer duty cycle than the full airgun arrays, firing every 30–45 seconds. Seismic activity will not ramp up from an extended shut-down (i.e., when the airgun has been down with no activity for at least 10 minutes) during nighttime operations and survey activities will be suspended until the following day because dedicated PSOs will not be on duty and any unseen animals may be exposed to injurious levels of sound from the full array. At night, the vessel captain and crew will maintain lookout for marine mammals and will order the airgun(s) to be shut down if marine mammals are observed in or about to enter the established safety radii.

(2) Safety and Disturbance Zones

NMFS mitigation or shutdown ''safety radii'' for limiting marine mammal exposure to impulse sources typically

correspond to the distances within which received sound levels are ≥180 dB_{rms} re 1 μPa for cetaceans and ≥190 dB_{rms} re 1 μPa for pinnipeds. These safety criteria are based on an assumption that SPLs received at levels lower than these will not injure these animals or impair their hearing abilities. Disturbance or behavioral effects to marine mammals from underwater sound may occur from exposure to sound at lower SPLs, at distances greater than the safety radii (Richardson *et al.,* 1995). The disturbance zone is defined as the area between the 180/190 dB threshold and the 160 dB threshold where NMFS has determined that harassment in the form of behavioral disturbance may occur.

The proposed survey will use airgun sources composed of two 2400 in^3 airguns, a single 440 in^3 airgun, and a single 10 in^3 airgun. Safety and disturbance radii for the sound levels produced by the planned airgun configurations and pinger have been estimated (see Table 1) and will be used for mitigation purposes during the seismic survey activities.

TABLE 1—ESTIMATED DISTANCES TO SOUND THRESHOLDS (APACHE WILL CONDUCT A SOUND SOURCE VERIFICATION STUDY TO DETERMINE THE ACTUAL DISTANCES TO THESE THRESHOLD ZONES)

Source	190 dB	180 dB	160 dB
Pinger	1 m	3 m	25 m
10 cui Airgun	10 m	33 m	330 m
440 cui Airgun	NA	NA	NA
2,400 cui airgun (nearshore)	0.51 km	1.42 km	6.41 km
2,400 cui airgun (offshore)	1.18 km	0.98 km	4.89 km

In addition to the marine mammal monitoring radii described above, pursuant to Alaska Department of Fish and Game restrictions, there will be a 1.6 km setback of sound source points from the mouths of any anadromous streams.

Apache also plans to use dedicated vessels to deploy and retrieve the nodal recording system. Sounds produced by the vessels are not expected to exceed 180 dB (rms). Therefore, mitigation related to acoustic impacts from these activities is not expected to be necessary.

(3) Power-downs

A power-down for mitigation purposes is the immediate reduction in the number of operating airguns such that the radii of the 190 dB rms and 180 dB rms zones are decreased to the extent that observed marine mammal(s) are not in the applicable safety zone of the full array. During a power-down, one airgun, typically the 10 in^3, continues firing. Operation of the 10 in^3 airgun decreases the safety radii to 10 m, 33 m, and 330 m for the 190 dB, 180 dB, and 160 dB zones, respectively. The continued operation of one airgun is intended to (a) alert marine mammals to the presence of the survey vessel in the area, and (b) retain the option of initiating a ramp up to full operations under poor visibility conditions (including nighttime).

The array will be immediately powered down whenever a marine mammal is sighted approaching close to or within the applicable safety zone of the full array, but is outside the applicable safety zone of the single mitigation airgun. Likewise, if a mammal is already within the safety zone when first detected, the airguns will be powered down immediately. If a marine mammal is sighted within or about to enter the applicable safety zone of the single mitigation airgun, it too will be shut down (see following section).

Following a power-down, operation of the full airgun array will not resume until the marine mammal has cleared the safety zone applicable to the full array. The animal will be considered to have cleared the safety zone if it

- Is visually observed to have left the safety zone of the full array, or
- Has not been seen within the zone for 15 min in the case of pinnipeds or small odontocetes (e.g., Steller sea lion, harbor seals, or harbor porpoises), or
- Has not been seen within the zone for 30 min in the case of large odontocetes (e.g., killer whales or beluga whales).

(4) Shut-downs

The operating airgun(s) will be shut down completely if a marine mammal approaches or enters the safety radius and a power-down is not practical or adequate to reduce exposure to less than 190 or 180 dB rms, as appropriate. In most cases, this means the mitigation airgun will be shut down completely if a marine mammal approaches or enters the estimated safety radius for the single 10 in^3 airgun while it is operating during a power down. Airgun activity will not resume until the marine mammal has cleared the safety radius. The animal will be considered to have cleared the safety radius as described above under power down procedures.

(5) Ramp Ups

A ramp up of an airgun array provides a gradual increase in sound levels, and involves a step-wise increase in the number and total volume of airguns firing until the full volume is achieved. The purpose of a ramp-up (or ''soft start'') is to ''warn'' undetected cetaceans and pinnipeds in the vicinity of the airguns and to provide the time for them to move far enough away from the airguns to avoid any potential injury or impairment of their hearing abilities.

During the proposed seismic survey, the seismic operator will ramp up the airgun array slowly. NMFS requires the rate of ramp-up to be no more than 6 dB per 5-minute period. Ramp-up is used at the start of airgun operations, after a power- or shut-down, and after any period of greater than 10 minutes in duration without airgun operations (i.e., extended shutdown).

A full ramp up after a shut down will not begin until there has been a minimum of 30 minutes of observation of the safety zone by PSOs to assure that no marine mammals are present. The entire safety zone must be visible during the 30-minute lead-in to a full ramp up. If the entire safety zone is not visible, then ramp up from a cold start cannot begin. If a marine mammal(s) is sighted within the safety zone during the 30-minute watch prior to ramp up, ramp up will be delayed until the marine mammal(s) is sighted outside of the safety zone or the animal(s) is not sighted for at least 15–30 minutes: 15 minutes for small odontocetes and pinnipeds (e.g. harbor porpoises, harbor seals, and Steller sea lions), or 30 minutes for large odontocetes (e.g., killer whales and beluga whales).

(6) Speed and Course Alterations

If a marine mammal is detected outside the applicable safety radius and, based on its position and the relative motion, is likely to enter the safety

radius, changes of the vessel's speed and/or direct course will be considered if this does not compromise operational safety. For marine seismic surveys using large arrays, course alterations are not typically possible. However, for the smaller airgun arrays planned during the proposed site surveys, such changes may be possible. After any such speed and/or course alteration is begun, the marine mammal activities and movements relative to the survey vessel will be closely monitored to ensure that the marine mammal does not approach within the relevant safety radius. If the mammal appears likely to enter the safety radius, further mitigative actions will be taken, including a power down or shut down of the airgun(s).

Additional Mitigation Measures Proposed by NMFS

Besides Apache's proposed mitigation measures discussed above, NMFS is requiring the following additional protective measures for beluga whale cow-calf pairs and aggregations of whales. This measure is designed to avoid exposing young animals to sounds levels which they may have never previously experienced and prevent the potential separation of mothers from their calves. In addition, because species like killer and beluga whales often travel in groups, the added protective measures for aggregations will avoid exposing groups of whales, which often contain calves, to harassment sounds levels produced during seismic surveys. Specifically, a 160-dB disturbance monitoring zone will be established and monitored in Cook Inlet during all seismic surveys. Whenever an aggregation of beluga whales or killer whales (five or more whales of any age/sex class) or a beluga cow-calf pair are observed approaching or within the 160-dB disturbance zone around the survey operations, the survey activity will not commence or will shut down, until they are no longer present within the 160-dB disturbance zone of seismic surveying operations.

Furthermore, NMFS requires the following measures in the IHA:

(1) All vessels will reduce speed when within 300 yards (274 m) of any whale, and those vessels capable of steering around such groups should do so. Vessels may not be operated in such a way as to separate members of a group of whales from other members of the group;

(2) Avoid multiple changes in direction and speed when within 300 yards (274 m) of whales; and

(3) When weather conditions require, such as when visibility drops, support vessels must adjust speed (increase or decrease) and direction accordingly to avoid the likelihood of injury to whales.

Mitigation Conclusions

NMFS has carefully evaluated the applicant's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Monitoring Measures

Apache will provide marine mammal monitoring to implement the mitigation measures that require real-time monitoring.

(1) Visual Vessel-Based Monitoring

Vessel-based monitoring for marine mammals will be done by experienced PSOs throughout the period of marine survey activities. PSOs will monitor the occurrence and behavior of marine mammals near the survey vessel during all daylight periods before, during, and after survey operations and during most daylight periods when airgun operations are not occurring. PSO duties will include watching for and identifying marine mammals, recording their numbers, distances, and reactions to the survey operations, and documenting takes incidental to the specified activity.

A sufficient number of PSOs will be required onboard the survey vessels to meet the following criteria: (1) 100 percent monitoring coverage during all periods of survey operations in daylight; (2) maximum of 4 consecutive hours on watch per PSO; and (3) maximum of 12 hours of watch time per day per PSO.

PSO teams will consist of experienced field biologists. An experienced field crew leader will supervise the PSO team onboard the survey vessel. Apache currently plans to have PSOs aboard the three vessels: the two source vessels (M/V *Peregrine Falcon* and M/V *Arctic Wolf*) and one support vessel (M/V *Dreamcatcher*). Two PSOs will be on the source vessels and two PSOs will be on the support vessel to observe the safety and disturbance zones. When marine mammals are about to enter or are sighted within designated safety zones, airgun or pinger operations will be powered down (when applicable) or shut down immediately. The vessel-based observers will watch for marine mammals during all periods when sound sources are in operation and for a minimum of 30 minutes prior to the start of airgun or pinger operations after an extended shut down.

Crew leaders and most other biologists serving as observers will be individuals with experience as observers during seismic surveys in Alaska or other areas in recent years.

The observer(s) will watch for marine mammals from the best available vantage point on the source and support vessels, typically the flying bridge. The observer(s) will scan systematically with the unaided eye and 7×50 reticle binoculars. Laser range finders will be available to assist with estimating distance. Personnel on the bridge will assist the observer(s) in watching for marine mammals.

All observations will be recorded in a standardized format. Data will be entered into a custom database using a notebook computer. The accuracy of the data will be verified by computerized validity data checks as the data are entered and by subsequent manual checks of the database. These procedures will allow for initial summaries of the data to be prepared during and shortly after the completion of the field program, and will facilitate transfer of the data to statistical, geographical, or other programs for future processing and achieving. When

a mammal sighting is made, the following information about the sighting will be recorded:

(A) Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from the PSO, apparent reaction to activities (e.g., none, avoidance, approach, paralleling, etc.), closest point of approach, and behavioral pace;

(B) Time, location, speed, activity of the vessel, sea state, ice cover, visibility, and sun glare; and

(C) The positions of other vessel(s) in the vicinity of the PSO location.

The ship's position, speed of support vessels, and water temperature, water depth, sea state, ice cover, visibility, and sun glare will also be recorded at the start and end of each observation watch, every 30 minutes during a watch, and whenever there is a change in any of those variables.

(2) Visual Shore-Based Monitoring

In addition to the vessel-based PSOs, Apache will utilize a shore-based station to visually monitor for marine mammals. The shore-based station will follow all safety procedures, including bear safety. The location of the shore-based station will need to be sufficiently high to observe marine mammals; the PSOs would be equipped with pedestal mounted ''big eye'' (20×110) binoculars. The shore-based PSOs would scan the area prior to, during, and after the airgun operations, and would be in contact with the vessel-based PSOs via radio to communicate sightings of marine mammals approaching or within the project area.

(3) Aerial-Based Monitoring

When survey operations occur near a river mouth, Apache will utilize the crew helicopter to conduct aerial surveys near river mouths prior to the commencement of airgun operations in order to identify locations where beluga whales congregate. The helicopter may also be used at other times. The types of helicopters currently planned for use by Apache include a Bell 407, Bell UH1B, and ASB3. Weather and scheduling permitting, aerial surveys will fly at an altitude of 305 m (1,000 ft). In the event of a marine mammal sighting, aircraft will attempt to maintain a radial distance of 457 m (1,500 ft) from the marine mammal(s). Aircraft will avoid approaching marine mammals from head-on, flying over or passing the shadow of the aircraft over the marine mammal(s). By following these operational requirements, sound levels received underwater are not expected to meet or exceed NMFS harassment thresholds (Richardson *et al.,* 1995; Blackwell *et al.,* 2002).

(4) Acoustic Monitoring

To further enhance detection of cetaceans, Apache will deploy passive acoustic monitoring (PAM) devices during the seismic survey. Apache anticipates utilizing the same system that was deployed during the 2D test program in March 2011 in Cook Inlet that was effective in detecting vocalizing belugas and harbor porpoises. Apache expects to deploy two PAM devices that will send real-time acoustic data via digital UHF radio-broadcast systems to the PAM operators aboard the M/V *Dreamcatche*r. The PAM operators will use specialized real-time detection software and audio playback to detect marine mammal sounds. If the PAM operators detect marine mammals, Apache will initiate a temporary shut-down of the airgun arrays to avoid takes. Following a shut-down, the airguns may be restarted in accordance with the ramp-up procedure described earlier.

Reporting Measures

(1) SSV Report

A report on the preliminary results of the acoustic verification measurements, including at a minimum the measured 190 =, 180 =, and 160 = dB_{rms} re 1 μPa radii of the airgun arrays and pinger, will be submitted within 120 hr after collection and analysis of those measurements at the start of the field season. This report will specify the distances of the exclusion zones that were adopted for the seismic survey activities.

(2) Field Reports

During the proposed survey program, the PSOs will prepare a report each day summarizing the recent results of the monitoring program. The field reports will summarize the species and numbers of marine mammals sighted. These reports will be provided to NMFS and to the survey operators on a weekly basis.

(3) Technical Report

The results of Apache's 2012 monitoring program, including estimates of ''take'' by harassment (based on presence in the 160 dB harassment zone), will be presented in a ''90-day'' and a Final Technical report. The Technical Report will include:

(a) Summaries of monitoring effort (e.g., total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals);

(b) Analyses of the effects of various factors influencing detectability of marine mammals (e.g., sea state, number of observers, and fog/glare);

(c) Species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover;

(d) Analyses of the effects of survey operations;

- Sighting rates of marine mammals during periods with and without seismic survey activities (and other variables that could affect detectability), such as:
- Initial sighting distances versus survey activity state;
- Closest point of approach versus survey activity state;
- Observed behaviors and types of movements versus survey activity state;
- Numbers of sightings/individuals seen versus survey activity state;
- Distribution around the source vessels versus survey activity state; and
- Estimates of take by Level B harassment based on presence in the 160 dB disturbance zone.

(4) Comprehensive Report

Following the survey season, a comprehensive report describing the vessel-based, shore-based, aerial-based, and acoustic monitoring programs will be prepared. The comprehensive report will describe the methods, results, conclusions and limitations of each of the individual data sets in detail. The report will also integrate (to the extent possible) the studies into a broad based assessment of industry activities, and other activities that occur in Cook Inlet, and their impacts on marine mammals. The report will help to establish long-term data sets that can assist with the evaluation of changes in the Cook Inlet ecosystem. The report will attempt to provide a regional synthesis of available data on industry activity in this part of Alaska that may influence marine mammal density, distribution and behavior.

(5) Notification of Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as an injury, serious injury or mortality (e.g., ship-strike, gear interaction, and/or entanglement), Apache will immediately cease the specified activities and immediately report the incident to the Chief of the Permits,

Conservation, and Education Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinators. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities will not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with Apache to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Apache may not resume their activities until notified by NMFS via letter, email, or telephone.

In the event that Apache discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (i.e., in less than a moderate state of decomposition as described in the next paragraph), Apache will immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators. The report must include the same information identified in the paragraph above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Apache to determine whether modifications in the activities are appropriate.

In the event that Apache discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Apache will report the incident to the Chief of the Permits, Conservation, and Education Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators, within 24 hours of the discovery. Apache will provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Estimated Take of Marine Mammals

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the proposed marine survey program. Anticipated impacts to marine mammals are associated with noise propagation from the sound sources (e.g., airguns and pingers) used in the seismic survey; no take is expected to result from the detonation of explosives onshore, as supported by the SSV study, or from vessel strikes.

Apache requests authorization to take five marine mammal species by Level B harassment. These five marine mammal species are: Cook Inlet beluga whale (*Delphinapterus leucas*); killer whale (*Orcinus orca*); harbor porpoise (*Phocoena phocoena*); harbor seal (*Phoca vitulina richardsi*), and Steller sea lion (*Eumetopias jubatus*).

The full suite of potential impacts to marine mammals was described in detail in the ''Potential Effects of the Specified Activity on Marine Mammals'' section found earlier in this document and in the notice of proposed IHA. The potential effects of sound from the proposed seismic survey might include one or more of the following: tolerance; masking of natural sounds; behavioral disturbance; non-auditory physical effects; and, at least in theory, temporary or permanent hearing impairment (Richardson *et al.,* 1995). The most common and likely impact will be from behavioral disturbance, including avoidance of the ensonified area or changes in speed, direction, and/or diving profile of the animal. Hearing impairment (TTS and PTS) are highly unlikely to occur based on the required mitigation and monitoring measures that would preclude marine mammals being exposed to noise levels high enough to cause hearing impairment.

For impulse sounds, such as those produced by airgun(s) and pingers used in the seismic survey, NMFS uses a received level of 160 dB_{rms} re 1 μPa to indicate the onset of Level B harassment. However, not all animals react to sounds at this level, and many will not show strong reactions (and in some cases any reaction) until sounds are stronger. Southall *et al.* (2007) provide a severity scale for ranking observed behavioral responses of both free-ranging marine mammals and laboratory subjects to various types of anthropogenic sound (see Table 4 in Southall *et al.* (2007)). Tables 7, 9, and 11 in Southall *et al.* (2007) outline the numbers of low-frequency cetaceans, mid-frequency cetaceans, and pinnipeds in water, respectively, reported as having behavioral responses to multi-pulses in 10-dB received level increments. These tables illustrate that while some studies have found moderate responses at these levels, some show that more severe reactions did not occur until sounds were much higher than 160 dB_{rms} re 1μPa.)

To estimate take by Level B harassment, Apache provided calculations for the size of the 160-dB isopleths and then overlaid those isopleths with the density of marine mammals in the total area ensonified within those isopleths over the time of the surveys. Apache provided a full description of the methodology used to estimate takes by harassment in its IHA application (see **ADDRESSES**), which is also provided in the following sections. NMFS used Apache's takes estimates in its analyses.

More specifically, to estimate takes by harassment, ranges to the 160 dB_{rms} re 1 μPa isopleths were estimated at three different water depths (5 m, 25 m, and 45 m) for nearshore surveys and at 80 m for channel surveys. The distances to these isopleths are provided in Table 1. The areas ensonified to the 160 dB isopleth for the nearshore survey are provided in Table 2. The area ensonifed to the 160 dB isopleth for the channel survey is 389 km^2.

TABLE 2—AREAS ENSONIFIED TO 160 dB FOR NEARSHORE SURVEYS

Nearshore survey depth classification	Depth range (m)	Area ensonifed to 160 dB (km^2)
Shallow	5–21	346
Mid-Depth	21–38	458
Deep	38–54	455

The following subsections describe how the estimated densities of marine mammals that may occur in the area were derived. It is important to note that, based on the comment letter received from the Marine Mammal Commission that pointed out errors in the density estimates for belugas, harbor porpoises, harbor seals, and Steller sea lions, the densities found in Table 4 below have changed since the notice of the proposed IHA (76 FR 58473, September 21, 2011). These corrected densities were used to estimate the number of Level B harassment takes incidental to the proposed activity.

Marine mammal densities near the planned activities in Cook Inlet were estimated from the annual aerial surveys conducted by NMFS between 2000 and 2010 for Cook Inlet beluga whales (Rugh *et al.,* 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007; Shelden *et al.,* 2008, 2009, 2010). These surveys are flown in June to collect abundance data for beluga whales, but sightings of other marine mammals are also reported, and these data were used for estimating the densities of the other species. Although these data are only collected in one month each year, and therefore do not account for seasonal variations in distribution or habitat use of each species, these surveys provide the best available relatively long-term data set for sighting information in the proposed action area. The general trend in marine mammal sightings is that beluga whales and harbor seals are seen most frequently in upper Cook Inlet, with higher concentrations of beluga whales near river mouths (particularly the Susitna River) and of harbor seals near haul out sites on Kalgin Island. The other marine mammals for which takes were estimated (killer whales, harbor porpoises, and Steller sea lions) are observed infrequently in upper Cook Inlet and more commonly in lower Cook Inlet. In addition, these densities are calculated based on a survey of a relatively large area, which is much larger than the survey site. Therefore, the use of these data to estimate density is considered to result in overestimates with respect to the probability of observing these animals in the action area. The maximum and average densities over the course of the total survey years (2000–2010) are provided in Table 3.

As discussed below, beluga whales are observed in higher concentrations near river mouths, particularly the Susitna River, due to feeding. Therefore, to account for the higher concentrations near river mouths, the highest number of beluga whales observed for each year was used to provide a density for river mouths. To account for the lower concentrations away from river mouths, the average number of beluga whales observed for each year was used to provide a density away from river mouths. A maximum and average density are provided to account for the inherent level of uncertainty in using aerial surveys conducted for a few days once a year in order to estimate density for the entire year.

TABLE 3—SUMMARY OF MARINE MAMMAL DENSITIES

Species	Density (number/km^2)	
	Maximum	Average
Beluga whale (average number observed)	0.00021	0.00011
Beluga whale (maximum number observed—rivers)	0.00128	0.00051
Harbor seal (total number observed)	0.00644	0.00317
Harbor porpoise (total number observed)	0.00037	0.00006
Killer whale (total number observed)	0.00011	0.00001
Steller sea lion (total number observed)	0.00035	0.00011

Below, we provide estimates of the number of individuals potentially exposed to sound levels ≥160 dB_{rms} re 1 μPa during seismic survey operations. The estimates were calculated by multiplying the expected densities by the anticipated area ensonified by levels ≥160 dB_{rms} re 1 μPa by the number of expected days that will be subject to seismic survey activities in the action area. According to section 2 in Apache's IHA application, a survey crew will collect seismic data 10–12 hours per day over approximately 160 days over the course of 8 to 9 months. Apache assumes that over the course of these 160 days, 100 days would be working in the offshore region and 60 days would be working in the shallow, intermediate, and deep nearshore region. Of those 60 days in the nearshore region, 20 days would be spent working in each of the three depths. Because operations would occur over 12 hours per day, but acoustic footprints were calculated based on 24 hours of survey activity (i.e., the distance a vessel would travel in 24 hours was used to calculate the square km ensonified in a day, and then that total was multiplied by the number of days that the survey vessel would be operating), the total number of days for each region was divided by two (or half a day) for purposes of calculating takes. It is important to note that environmental conditions (such as ice, wind, and fog) will play a significant role in the actual number of operating days; therefore, these estimates, which are based on the best case scenario and optimal environmental conditions, likely overestimate the probability of encountering these marine mammal species in the action area because the actual number of operating are likely to be fewer.

The number of estimated takes by Level B harassment was calculated using the following assumptions:

- The number of nearshore and shallow water survey days is 10 (20 days/12 hours) and daily acoustic footprint is 356 km².
- The number of nearshore and intermediate water depth survey days is 10 (20 days/12 hours) and daily acoustic footprint is 468 km².
- The number of nearshore and deep water depth survey days is 10 (20 days/12 hours) and daily acoustic footprint is 455 km².
- The number of offshore survey days is 50 (100 days/12 hours) and daily acoustic footprint is 389 km².

As noted above, Apache modeled the acoustic footprints of the airgun arrays in order to estimate the 160 dB isopleth. The modeling report is attached to the IHA application as Appendix A and summarized below. The nearshore locations were sub-divided into the following three depth intervals because of the sloping bottom contour along the sides of Cook Inlet: 5–21 m; 21–38 m; and 38–54 m. Due to the relatively constant depth in the Inlet's main channel, the channel scenario used a water depth of 80 m. The nearshore survey depth interval subdivisions are based on the zones that can be surveyed in 24 hour periods based on the anticipated nominal survey length of 16.1 km, and survey line spacing of 503 m. Apache estimates that it can complete 12–14 survey lines per day based on normal survey vessel speed (approximately 2–4 knots). The depth intervals each correspond with 14 adjacent parallel lines based on the rate of depth increase with distance from shore. The different depth intervals were considered separately because the size of the airgun array sound footprint varies with water depth. The largest possible airgun array configuration of 2400 cui was applied to model the noise footprints used in the take calculations, which means that the 160-dB isopleths are likely overestimates when applied to the small arrays that may be used during the actual survey.

The nearshore modeling scenarios were examined by placing the source at three distances offshore corresponding to the following water depths: 5, 25, and 45 m. For each source position, the model predicted distances to the 160 dB re μ1 Pa (rms) threshold in multiple directions. These distances were subsequently interpolated to predict threshold distances for survey source positions at all depths between 5 m and 54 m. The deep channel survey scenario, with a constant water depth of 80 m, was modeled to predict the distances in the endfire and broadside directions relative to the array where sound levels attenuated to 160 dB re μ1 Pa (rms).

The 24-hour composite acoustic footprints were calculated from the footprints of the individual survey lines. Each survey line footprint was estimated using a rectangle that encompassed the 160 dB broadside (in shore and offshore directions) and endfire (along-shore) extents for all airgun pulses on that line. The union of 14 survey line footprints created the 24-hour composite acoustic footprint. The union of the single line footprint is smaller than their sum because of overlap.

Table 4 shows the estimated maximum and average exposures to levels above 160dB by species for the first year of seismic surveys in Cook Inlet based on the assumptions outlined above. However, when the density and distribution data for certain species are considered more carefully, as well as the likely effect of the required mitigation measures, the take estimates may be further refined as illustrated by the requested and authorized number of takes below.

The use of the NMFS aerial survey data has inherent weaknesses that need to be considered. For example, the estimated number of harbor seal takes by Level B harassment is higher than what is actually anticipated because there are no haul-out sites within the action area. Seals in some numbers are expected to be observed in the Susitna River delta, but not in the large numbers that are observed in lower Cook Inlet. The density estimates used to calculate take are skewed upward by the numbers observed in large haul outs during aerial surveys. Seals in the water usually travel in small groups or as single individuals; therefore, although Table 4 indicates an average of 102 and maximum of 207 seals exposed to sounds likely to result in Level B harassment, it is highly unlikely that those number of seals will actually be taken during the proposed seismic survey. To account for the likely overestimate of takes by Level B harassment due to the location of the seismic survey and lack of haul-out sites in the vicinity, Apache requested and NMFS authorizes 50 takes instead.

Similarly, NMFS expects the number of actual Steller sea lion takes by Level B harassment to be lower than the average of four and maximum of 11 indicated in Table 4. During the NMFS aerial surveys, no Steller sea lions were observed in upper Cook Inlet. Less than five Steller sea lions have been observed by the Port of Anchorage monitoring program, and those observed have been juvenile animals (likely male). Apache estimated that there could be 11 Steller sea lions takes by Level B harassment in the proposed action area during the one-year effective period of the IHA; nevertheless, to account for variability and anomalous years where higher than average numbers of Steller sea lions are reported in Cook Inlet, Apache requests and NMFS authorizes 20 takes by Level B harassment.

The average and maximum take estimates for harbor porpoise and killer whales shown in Table 4. Although the actual number of animals expected to be encountered during seismic survey activities is lower, Apache requests and NMFS authorizes 20 takes of harbor porpoises and 10 takes of killer whales—both by Level B harassment only—to account for annual variability in abundance and distribution in Cook Inlet.

The average and maximum estimated number of takes by Level B harassment for Cook Inlet beluga whales away from river mouths is two and five, respectively. Given that beluga are usually transiting from one feeding area to another in lower concentrations, these estimates appear to be reasonable in assessing the probability for potentially observing beluga whales in the action area. However, it is important to note that a combination of visual and acoustic monitoring will be used extensively throughout this project, particularly for detecting beluga whales approaching the area, and to trigger shutdowns and powerdowns of sound sources, which also has the potential to reduce the actual number of takes.

The average and maximum estimated number of takes by Level B harassment for Cook Inlet beluga whales near river mouths is 16 and 41 animals, respectively. The total number of days actually surveying near river mouths (60 days in the shallow, intermediate, and deep nearshore region) is much lower than the 160 days used to estimate takes in the different water depths, and again, the estimate does not take into account mitigation; therefore, this take estimate is likely to be an overestimate. As a result, due to the actual number of days and hours Apache is likely to be operating airguns near river mouths and taking into account the monitoring and mitigation measures applicable when operating seismic survey equipment near rivers, Apache expects the actual number of takes by Level B harassment estimated for Cook Inlet beluga whales to be much lower than the numbers provided in Table 4. To account for this, Apache requests and NMFS authorizes

30 takes of Cook Inlet beluga whale by Level B harassment.

TABLE 4—ESTIMATED TAKES BY LEVEL B HARASSMENT PER SPECIES (WITHOUT MITIGATION)

Species	Shallow		Mid-depth		Deep		Offshore		Total	
	Max	Avg	Max	Avg	Max	Avg	Max	Avg	Max	Avg
Beluga whales—away from river mouths	0.5	0.3	0.7	0.3	0.7	0.3	2.8	1.5	4.7	2.4
Beluga whales—near river mouths	4.5	1.8	5.8	2.3	5.8	2.3	24.8	9.9	41	16.3
Harbor seals	22.9	11.3	29.5	14.5	29.3	14.4	125.3	61.7	207	101.9
Harbor porpoises	1.3	0.2	1.7	0.3	1.7	0.3	7.2	1.2	11.9	2.0
Killer whales	0.4	0.1	0.5	0.1	0.5	0.1	2.2	0.3	3.6	0.5
Steller sea lions	1.2	0.4	1.6	0.5	1.6	0.5	6.8	2.2	11.3	3.7

TABLE 5—AUTHORIZED NUMBER OF TAKES BY LEVEL B HARASSMENT

Species	Number of requested takes	Population abundance	Percent of population
Beluga whales	30	284	10
Harbor seals	50	29,175	0.17
Harbor porpoises	20	31,406	0.06
Killer whales	10	1,123	0.89
Steller sea lions	20	41,197	0.12

Negligible Impact and Small Numbers Analysis and Determination

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the takes occur.

Given the required mitigation and related monitoring, no injuries or mortalities are anticipated to occur as a result of Apache's proposed seismic survey in Cook Inlet, and none are proposed to be authorized. Additionally, animals in the area are not expected to incur hearing impairment (i.e., TTS or PTS) or non-auditory physiological effects. The small number of takes that are anticipated are expected to be limited to short-term Level B behavioral harassment. Although it is possible that some marine mammals individuals may be exposed to sounds from seismic survey activities more than once, the duration of these multi-exposures is expected to be low since both the animals and the survey vessels will be moving constantly in and out of the survey area and the seismic airguns do not operate continuously all day, but for a few hours at a time totaling about 12 hours a day.

Odontocete (including Cook Inlet beluga whales, killer whales, and harbor porpoises) reactions to seismic energy pulses are usually assumed to be limited to shorter distances from the airgun(s) than are those of mysticetes, in part because odontocete low-frequency hearing is assumed to be less sensitive than that of mysticetes. However, at least when in the Canadian Beaufort Sea in summer, belugas appear to be fairly responsive to seismic energy, with few being sighted within 6–12 mi (10–20 km) of seismic vessels during aerial surveys (Miller *et al.* 2005). Due to the more dispersed distribution of beluga whales when Apache plans to commence its seismic surveys and the concentration of animals in the upper Inlet during spring and summer in response to the presence of prey species such as eulachon and salmon, belugas will likely occur in small numbers in Cook Inlet during the survey period and few will likely be affected by the survey activity in a manner that would be considered behavioral harassment. For the same reason, it is unlikely that any individual animal would be exposed to higher received levels multiple times.

Taking into account the mitigation measures that are planned, effects on cetaceans are generally expected to be restricted to avoidance of a limited area around the survey operation and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment''. Animals are not expected to permanently abandon the area, and any behaviors that are interrupted during the survey are expected to resume once the activity ceases. In addition, the area where the survey will take place is not known to be an important location where beluga whale congregate for feeding, calving, or nursing. Additionally, one of the mitigation measures specifically requires shut down of the airguns if a calf, or an aggregation of 5 or more beluga whales, is detected anywhere within the area where marine mammals would be expected to be behaviorally harassed by the sound levels Furthermore, the estimated numbers of animals potentially exposed to sound levels sufficient to cause Level B harassment are low percentages of the population sizes, as illustrated above in Table 5. Therefore, the exposure of cetaceans to sounds produced by the proposed seismic survey in Cook Inlet is not anticipated to have an effect on annual rates of recruitment or survival.

Some individual pinnipeds may be exposed to sound from the proposed marine surveys more than once during the time frame of the project, but there are no know pinniped rookeries or haulouts in the vicinity of the survey site. As discussed previously, the exposure of pinnipeds to sounds produced by the proposed seismic survey in Cook Inlet is not expected to result in more than short-term Level B harassment of a low percentage of the affected species, and is not anticipated to have an effect on annual rates of recruitment or survival.

Mitigation and monitoring measures such as controlled vessel speed, dedicated marine mammal observers, non-pursuit, ramp-up, and shut downs or power downs when marine mammals are seen within defined ranges or belugas are seen in certain groupings (calf or aggregation of 5 or more) at even greater ranges will further reduce both the number and severity of behavioral impacts and minimize any potential for effects on hearing sensitivity. In all cases, the effects are expected to be relatively short-term and limited to Level B harassment that is not expected to affect annual rates of recruitment or survival for any marine mammals.

Potential impacts to marine mammal habitat were discussed previously in this document (see the ''Anticipated Effects on Habitat'' section). Although some temporary acoustic disturbance is possible to food sources of marine mammals, the impacts are anticipated to be short term and minor enough (and not focused either in primary feeding areas or areas where many belugas are feeding at the time of the activity) that they would only have temporary behavioral impacts, and no lasting energetic impacts. Based on the size of Cook Inlet where feeding by marine mammals occurs versus the localized area of the marine survey activities, any missed feeding opportunities in the direct project area would be minor based on the fact that other feeding areas exist elsewhere throughout Cook Inlet.

The requested takes proposed to be authorized represent 10 percent of the Cook Inlet beluga whale population of approximately 284 animals (Hobbs *et al.,* 2011), 0.89 percent of the combined Alaska resident stock and Gulf of Alaska, Aleutian Island and Bering Sea stock of killer whales (1,123 residents and 314 transients), and 0.06 percent of the Gulf of Alaska stock of approximately 31,046 harbor porpoises. The take requests presented for harbor seals represent 0.17 percent of the Gulf of Alaska stock of approximately 29,175 animals. Finally, the requested takes proposed for Steller sea lions represent 0.12 percent of the western DPS of approximately 41,197 animals. These percentage estimates represent small numbers relative to the affected population sizes, and they represent the percentage of each species or stock that could be taken by Level B behavioral harassment if each animal is taken only once. In addition, the mitigation and monitoring measures in the IHA are expected to reduce even further these numbers by requiring that sources shut down for aggregations of five or more whales and/or beluga calf-cow pairs before they enter the Level B harassment take zone.

Based on the analysis contained in this notice of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS finds that Apache's seismic survey in Cook Inlet may result in the incidental take of small numbers of marine mammals, by Level B harassment only, and that the total taking from the survey will have a negligible impact on the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Section 101(a)(5)(D) requires NMFS to determine that the authorization will not have an unmitigable adverse effect on the availability of marine mammal species or stocks for subsistence use. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as: An impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The subsistence harvest of marine mammals transcends the nutritional and economic values attributed to the animal and is an integral part of the cultural identity of the region's Alaska Native communities. Inedible parts of the whale provide Native artisans with materials for cultural handicrafts, and the hunting itself perpetuates Native traditions by transmitting traditional skills and knowledge to younger generations (NOAA 2007). However, due to dramatic declines in the Cook Inlet beluga whale population, on May 21, 1999, legislation was passed to temporarily prohibit (until October 1, 2000) the taking of Cook Inlet belugas under the subsistence harvest exemption in section 101(b) of the MMPA without a cooperative agreement between NMFS and the affected Alaska Native Organizations (ANOs) (Pub. L. No. 106–31, section 3022, 113 Stat. 57,100). That prohibition was extended indefinitely on December 21, 2000 (Public Law No. 106–553, section 1(a)(2), 114 Stat. 2762). NMFS subsequently entered into six annual co-management agreements (2000–2003, 2005–2006) with the Cook Inlet Marine Mammal Council, an ANO representing Cook Inlet beluga hunters, which allowed for the harvest of 1–2 belugas. On October 15, 2008, NMFS published a final rule that established long-term harvest limits on the Cook Inlet beluga whales that may be taken by Alaska Natives for subsistence purposes (73 FR 60976). That rule prohibits harvest for a 5-year period (2008–2012), if the average abundance for the Cook Inlet beluga whales from the prior five years (2003–2007) is below 350 whales. The next 5-year period that could allow for a harvest (2013–2017), would require the previous five-year average (2008–2012) to be above 350 whales.

There is a low level of subsistence hunting for harbor seals in Cook Inlet. Seal hunting occurs opportunistically among Alaska Natives who may be fishing or travelling in the upper Inlet near the mouths of the Susitna River, Beluga River, and Little Susitna River.

Consistent with NMFS' implementing regulations, Apache met with the CIMMC—the marine mammal ANO that represents Cook Inlet tribes—on March 29, 2011, to discuss the proposed activities and discuss subsistence concerns. Apache also met with the Tyonek Native Corporation on November 9, 2010, and the Salamat of Native Corporation on November 22, 2010. Additional meetings were held with the Native Village of Tyonek, the Kenaitze Indian Tribe, the Knik Tribal Council, and the Ninilchik Traditional Council. According to Apache, during all these meetings, no concerns were stated regarding potential conflict with subsistence harvest of marine mammals. Apache has identified the following features that are intended to reduce impacts to marine mammal subsistence users:

- In-water seismic activities will follow mitigation procedures to minimize effects on the behavior of marine mammals and, therefore, opportunities for harvest by Alaska Native communities;
- Regional subsistence representatives may support recording marine mammal observations along with marine mammal biologists during the monitoring programs and will receive marine mammal observation reports.

Apache concluded, and NMFS agrees, that the size of the affected area, mitigation measures, and input from the consultations with CIMMC and Alaska Natives should result in the proposed action having no effect on the availability of marine mammals for subsistence uses. Apache and NMFS

recognize the importance of ensuring that Alaska Native Organizations and federally recognized tribes are informed, engaged, and involved during the permitting process and will continue to work with the ANOs and tribes to discuss their operations and activities.

On February 6, 2012, in response to requests for government to government consultations by the CIMMC and Native Village of Eklutna, NMFS met with representatives from these two groups and a representative from the Ninilchik. We engaged in discussions about the proposed IHA, the MMPA process for issuing an IHA, concerns regarding Cook Inlet beluga whales, and achieving greater coordination with NMFS on issues that impact tribal concerns. NMFS considered these communications before issuing its IHA.

NMFS anticipates that any effects from Apache's seismic survey on marine mammals, especially harbor seals and endangered Cook Inlet beluga whales, which are or have been taken for subsistence uses, would be short-term, site-specific, and limited to inconsequential changes in behavior and mild stress responses. NMFS does not anticipate that the authorized taking of affected species or stocks will reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (1) Causing the marine mammals to abandon or avoid hunting areas; (2) directly displacing subsistence users; or (3) placing physical barriers between the marine mammals and the subsistence hunters; and that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met. Therefore, NMFS has determined that the authorized taking will not have an unmitigable adverse impact on the availability of Cook Inlet marine mammal stocks for subsistence uses.

Endangered Species Act (ESA)

There are two marine mammal species listed as endangered under the ESA with confirmed or possible occurrence in the proposed project area: the Cook Inlet beluga whale and western DPS of Steller sea lion. On September 2, 2011, NMFS' Permits and Conservation Division initiated consultation with NMFS' Protected Resources Division under section 7 of the ESA on the issuance of an IHA to Apache under section 101(a)(5)(D) of the MMPA for this activity. Consultation was concluded and a biological opinion issued prior to issuance of the IHA. That biological opinion determined the proposed action is not likely to jeopardize the continued existence of the Cook Inlet beluga whales or the western DPS of Steller sea lions, or to destroy or adversely modify Cook Inlet beluga whale critical habitat.

National Environmental Policy Act (NEPA)

NMFS prepared an Environmental Assessment to determine whether this proposed activity will have a significant effect on the human environment. This analysis was completed prior to the issuance of the IHA with NMFS' issuance of a Finding of No Significant Impact (FONSI).

Authorization

NMFS has issued an incidental harassment authorization for the take of marine mammals incidental to Apache's seismic survey in Cook Inlet, Alaska, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: May 4, 2012.

Helen M. Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

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BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 6/11/2012.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 9/23/2011 (76 FR 59117–59118); 3/9/2012 (77 FR 14352–14353); and 3/16/2012 (77 FR 15736), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN: 7510–00–079–7905—Package Sealing Tape, Tan.
NPA: Cincinnati Association for the Blind, Cincinnati, OH.
Contracting Activity: General Services Administration, New York, NY.
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.

NSN: 5640–01–386–9618—Sound Controlling Blanket, 24″Wx54″L.
NPA: Genesee County Chapter, NYSARC, Batavia, NY.
Contracting Activity: General Services Administration, Fort Worth, TX.
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.

Services

Service Type/Location: Custodial & Pest Control Services, Naval Operations Support Center (NOSC), 3623 Carolina Beach Rd., Wilmington, NC.
NPA: OE Enterprises, Inc., Hillsborough, NC.
Contracting Activity: Dept of the Navy, Naval FAC Engineering CMD MID LANT, Norfolk, VA.

Service Type/Location: Janitorial Services,

Kahului Airport, 1 Airport Road, Kahului, HI.
NPA: Ka Lima O Maui, Ltd., Wailuku, HI.
Contracting Activity: Department of Homeland Security, Transportation Security Administration, Office of Acquisition, Arlington, VA.

Service Type/Location: Fleet Service, Naval Research Laboratory, 4555 Overlook Avenue SW., Washington, DC.
NPA: Skookum Educational Programs, Bremerton, WA.
Contracting Activity: Dept of the Navy, Naval Research Laboratory, Washington, DC.

Service Type/Location: Laundry, Refurbishment, and Warehouse Services, Army Contracting Command, 6501 E. 11 Mile Road, Warren, MI.
NPA: Peckham Vocational Industries, Inc., Lansing, MI.
Contracting Activity: Dept of the Army, W4GG HQ US Army TACOM, Warren, MI.

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2012–11413 Filed 5–10–12; 8:45 am]
BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add services to the Procurement List that will be provided by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes a product and service previously furnished by such agencies.

Comments Must Be Received On or Before: 6/11/2012.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

For Further Information or To Submit Comments Contact: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will provide the services to the Government.
2. If approved, the action will result in authorizing small entities to provide the services to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Record Processing Services, Army Medical Department, Patient Administrative Division, MEDCOM, Fort Sam Houston, TX.
NPA: Goodwill Industries of San Antonio, San Antonio, TX.
Contracting Activity: Medcom Health Care Contracting, Fort Sam Houston, TX.

Service Type/Location: Custodial Service, Child Care Facilities, Buildings 615, 616 and 9625, Fort Leonard Wood, MO.
NPA: Challenge Unlimited, Inc., Alton, IL.
Contracting Activity: DEPT OF THE ARMY, W6QM MICC–FT LEONARD WOOD, FORT LEONARD WOOD, MO.

Service Type/Location: Document Destruction Service, U.S. Department of Agriculture, 6200 Jefferson St. NE., Albuquerque, NM.
NPA: Adelante Development Center, Inc., Albuquerque, NM.
Contracting Activity: Department of Agriculture, Natural Resources Conservation Service, Soil Conservation Service, Albuquerque, NM.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. If approved, the action may result in authorizing small entities to furnish the product and service to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product and service proposed for deletion from the Procurement List.

End of Certification

The following product and service are proposed for deletion from the Procurement List:

Product

NSN: 7520–01–585–0981—Calendar, Wall, Monthly Undated/Yearly Dated.
NPA: The Chicago Lighthouse for People Who Are Blind or Visually Impaired, Chicago, IL.
Contracting Activity: General Services Administration, Arlington, VA.

Service

Service Type/Location: Janitorial/Custodial, South Weymouth Naval Air Station: Caretaker Site Office, Naval Air Station, South Weymouth, MA.
NPA: Community Workshops, Inc., Boston, MA.
Contracting Activity: Dept of the Navy, Naval FAC Engineering CMD MID LANT, Norfolk, VA.

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2012–11412 Filed 5–10–12; 8:45 am]
BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add services to the Procurement List that will be provided by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received On or Before: 6/11/2012.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800,

1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will provide the services to the Government.

2. If approved, the action will result in authorizing small entities to provide the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Mess Attendant, Joint Expeditionary Base (JEB) Little Creek, Ft Story East Campus, Light House Cafe, Building 864, 864 Hospital Road, Virginia Beach, VA.
NPA: Community Alternatives, Incorporated, Norfolk, VA.
Contracting Activity: Dept of the Navy, NAVSUP FLT LOG CTR Norfolk, Norfolk, VA.

For this project, the DOD contracting activity specifically identified its requirement as Mess Attendant Service in its Performance Work Statement (PWS). The PWS describes Mess Attendant service tasks as post cleaning of eating utensils, compartmented trays, beverage containers, insulated food containers and inserts, full vegetable preparation; prepare, maintain, and clean dining areas; clean condiment containers, clean spills and remove soiled dinnerware, clean dining room tables, chairs, and booths, clean dining room walls, baseboards, window ledges, doors/door frames, ceiling fans, pictures, wall art, artificial plants, light fixtures, globes/lenses, trophies/display cases, drapes/curtains, venetian blinds and curtain rods; display and remove holiday decorations, buss and replace tray carts during meal periods, service and maintain patron self-service areas, clean food service equipment, utensils, and perform dishwashing, clean and sanitize all pots, pans, utensils, storage shelves, and racks; provide equipment cleaning service, perform facility maintenance and sanitation; provide trash and garbage service; preparation of facilities for pest control fogging; provide pre-opening and post vector control clean-up services.

Service Type/Location: Custodial Services, Caribou-Targhee National Forest, St. Anthony Supervisor's Office, U.S. Forest Service, 499 N 2400 E St., St. Anthony, ID.
NPA: Development Workshop, Inc., Idaho Falls, ID.
Contracting Activity: Dept of Agriculture, Forest Service, Caribou-Targhee National Forest, Idaho Falls, ID.
Service Type/Location: Custodial and Grounds Services, Armed Forces Medical Examiner System, Building 115, 115 Purple Heart Drive, Dover AFB, DE.
NPA: The Chimes, Inc., Baltimore, MD.
Contracting Activity: Dept of the Army, W4PZ USA MED RSCH ACQUIS ACT, Fort Detrick, MD.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2012–11414 Filed 5–10–12; 8:45 am]

BILLING CODE 6353–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Proposed Collection; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comments.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the Bureau is soliciting comments concerning the information collection efforts relating to the qualitative testing mortgage servicing related model forms and disclosures.

DATES: Written comments must be received on or before July 10, 2012 to be assured of consideration.

ADDRESSES: You may submit comments by any of the following methods:

- *Electronic: CFPB_Public_PRA@cfpb.gov.*
- *Mail/Hand Delivery/Courier:* Direct all written comments to Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.

Instructions: Comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552 on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect comments by telephoning (202) 435–7275. All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. You should only submit information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the documents contained under this approval number should be directed to Joseph Durbala, (202) 435–7893, at the Consumer Financial Protection Bureau, (Attention: Joseph Durbala, PRA Office), 1700 G Street NW., Washington, DC 20552, or through the Internet at *CFPB_Public_PRA@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

Title: Qualitative Testing of Mortgage Servicing Related Model Forms and Disclosures.

OMB Number: 3170–0018.

Abstract: The Bureau seeks to allow for qualitative testing of mortgage servicing related model forms and disclosures. The research will result in the development of, and revisions to, proposed and final model forms and disclosures provided to consumers in connection with mortgage loan obligations after origination. The research activities will be conducted primarily by an external contractor employing cognitive psychological testing methods. This approach has been demonstrated to be feasible and valuable by the CFPB and other agencies in developing disclosures and other forms. The planned research activities will be conducted during FY 2012–2013 with the goal of creating effective disclosures and related materials for

consumers regarding mortgage loan obligations after origination.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households.

Estimated Number of Responses: 396.

Estimated Time per Respondent: 16 minutes.

Estimated Total Annual Burden Hours: 108.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and the assumptions used; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Dated: May 2, 2012.

Chris Willey,

Chief Information Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2012–11369 Filed 5–10–12; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

National Security Education Board Members Meeting

AGENCY: Under Secretary of Defense Personnel and Readiness, DoD.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given of a forthcoming meeting of the National Security Education Board. The purpose of the meeting is to review and make recommendations to the Secretary of Defense concerning requirements established by the David L. Boren National Security Education Act, Title VII of Public Law 102–183, as amended.

DATES: June 20, 2012, from 8:30 a.m.–2:00 p.m.

ADDRESSES: Defense Language and National Security Education Office, 1101 Wilson Boulevard, Suite 1210, Arlington, VA 22209.

FOR FURTHER INFORMATION CONTACT: Ms. Alison Patz, Program Analyst, Defense Language and National Security Education Office (DLNSEO), 1101 Wilson Boulevard, Suite 1210, Arlington, Virginia 22209–2248; (703) 696–1991. Electronic mail address: *Alison.patz@wso.whs.mil.*

SUPPLEMENTARY INFORMATION: The National Security Education Board Members meeting is open to the public. The public is afforded the opportunity to submit written statements associated with DLNSEO.

Dated: May 7, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–11331 Filed 5–10–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–OS–0055]

Privacy Act of 1974; System of Records

AGENCY: Defense Threat Reduction Agency, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Defense Threat Reduction Agency proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action would be effective on June 11, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Juanita Gaines, Freedom of Information and Privacy Office, Defense Threat Reduction Agency, 8725 John J. Kingman Road, Fort Belvoir, VA 22060–6201 or by phone at (703) 767–1771.

SUPPLEMENTARY INFORMATION: The Defense Threat Reduction Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on May 1, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: May 8, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

HDTRA 010

SYSTEM NAME:

Nuclear Test Participants (October 26, 2009, 74 FR 54975).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''Nuclear Test Personnel Review (NTPR) Office, Defense Threat Reduction Agency, 8725 John J. Kingman Road, Fort Belvoir, VA 22060–6201.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''U.S. Veterans who were military members on active duty, and DoD civilians who were participants of the U.S. nuclear testing programs, assigned to Hiroshima or Nagasaki from August 6, 1945 to July 1, 1946; and DoD contractors and foreign

nationals who participated in the cleanout of Enewetak Atoll.''

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with ''In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

National Research Council and Vanderbilt University for the purpose of conducting epidemiological studies on the effects of ionizing radiation on participants of nuclear test programs.

Department of Labor and the Department of Justice for the purpose of processing claims by individuals who allege job-related disabilities as a result of participation in nuclear test programs and for litigation actions.

Department of Energy (DOE) for the purpose of identifying DOE and DOE contractor personnel who were, or may be in the future, involved in nuclear test programs; and for use in processing claims or litigation actions.

Department of Veterans Affairs for the purpose of processing claims by individuals who allege service-connected disabilities as a result of participation in nuclear test programs and for litigation actions' and to conduct epidemiological studies on the effect of radiation on nuclear test participants.

Upon appropriate identification or with proper authorization, information may be released to veterans or their authorized representatives.

Veterans Advisory Board on Dose Reconstruction for the purposes of reviewing and overseeing the Department of Defense Radiation Dose Reconstruction Program, to include the conduct of audits of dose reconstructions and decisions by the Department of Veterans Affairs (DVA) on claims for radiogenic diseases and the provision of assistance to both the DVA and the DTRA in providing information on the Program, and such other activities as authorized by the Veterans Benefits Act of 2003 (Pub. L. 108–183, section 601).

The DoD ''Blanket Routine Uses'' published at the beginning of DTRA's compilation of system of records notices apply to this system.

Note: This system of records contains Personal Identifiable Information. The DoD Health Information Privacy Regulation (DoD 6025.18–R) issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information. DoD 6025.18–R may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice.''

* * * * *

STORAGE:

Delete entry and replace with ''Paper records and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''Name, SSN, or service number.''

SAFEGUARDS:

Delete entry and replace with ''Paper records are filed in folders, microfilm/fiche and computer printouts stored in areas accessible only by authorized personnel. Buildings are protected by security guards and intrusion alarm systems. Magnetic tapes are stored in a vault in a controlled area within limited access facilities. Access to computer programs is controlled through software applications which require validation prior to use. Electronic files are password protected or encrypted.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Records are retained for 75 years after termination of case. Paper and microfiche records are collected in official disposal containers (burn-bags here at Fort Belvoir, and certified records disposal containers (contract service) at Nuclear Test Personnel Review Office (NTPR)'s offsite contract sites). With regard to magnetic tape (or hard disk drives) bulk demagnetizers are used to clean the disks/tape before they are turned over to DTRA logistics for disposal. Electronic files are to be electronically transferred to NARA when no longer required.''

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Retired Military Personnel records from the National Personnel Records Center, US DTRA Form 150 from individuals voluntarily contacting DTRA or other elements of DoD or other Government Agencies by phone or mail. DoD historical records, dosimetry records and records from the Department of Energy, Department of Veterans Affairs, the Social Security Administration, the Internal Revenue Service, and the Department of Health and Human Services.''

* * * * *

[FR Doc. 2012–11452 Filed 5–10–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–OS–0054]

Privacy Act of 1974; System of Records

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Defense Logistics Agency proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action would be effective on June 11, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler, Privacy Act Officer, Headquarters Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221, or by phone at (703) 767–5045.

SUPPLEMENTARY INFORMATION: The Defense Logistics Agency systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 27, 2012 to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities

for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: May 8, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

S400.20

SYSTEM NAME:

Day Care Facility Registrant, Applicant and Enrollee Records (August 29, 2008, 73 FR 50949).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Children and their sponsors (DoD personnel, active duty military, and DoD contractors) who are enrolled in, or have applied for admission to, DLA-managed day care facilities.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete ''Social Security Numbers'' from the ''Waiting List Applicant Records'' paragraph and ''Social Security Number (SSN)'' from the ''Employee Records'' paragraph.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete ''E.O. 9397 (SSN)'' from entry.

PURPOSE(S):

Within entry, replace ''CDP'' with ''Child Development and Youth Program (CDYP)'' the first time; thereafter replace ''CDP'' with ''CDYP.''

* * * * *

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

Delete element in its entirety.

* * * * *

STORAGE:

Delete ''and in electronic storage media''.

RETRIEVABILITY:

Delete ''and Social Security Number''.

SAFEGUARDS:

Delete last sentence in entry.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Change attention element to ''ATTN: DS–Q.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the DLA HQ FOIA/Privacy Act Office, Defense Logistics Agency Headquarters, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Inquiries from registrants/applicants/sponsors should contain their full name and address. Inquiries from volunteers should contain their full name.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the DLA HQ FOIA/Privacy Act Office, Defense Logistics Agency Headquarters, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Inquiries from registrants/applicants/sponsors should contain their full name and address. Inquiries from volunteers should contain their full name.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the DLA HQ FOIA/Privacy Act Office, Defense Logistics Agency Headquarters, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.''

RECORD SOURCE CATEGORIES:

Change ''CDP'' to ''Child Development and Youth Program.''

* * * * *

[FR Doc. 2012–11419 Filed 5–10–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2012–0010]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to delete three systems of records.

SUMMARY: The Department of the Army is deleting three systems of records notices in its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on June 11, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments.

- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones, Jr., Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22315–3827, or by phone at 703–428–6185.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed deletions are not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: May 8, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Deletions

A0351a IRMC

Information Resources Management College Record System (December 18, 2001, 66 FR 65180).

REASON:

The Information Resources Management College Records System has now transferred to the National Defense University. All associated records are covered under SORN DNDU 01 (September 21, 2010, 75 FR 57458). Therefore, the system of records notice can be deleted.

A0351b IRMC

IRMC Student/Faculty/Senior Staff Biography System (December 18, 2001, 66 FR 65180).

REASON:

The IRMC Student/Faculty/Senior Staff Biography System has now

transferred to the National Defense University. All associated records are covered under SORN DNDU 01 (September 21, 2010, 75 FR 57458). Therefore, the system of records notice can be deleted.

A0351c IRMC

IRMC Course Evaluation System (December 18, 2001, 66 FR 65180).

REASON:

The IRMC Course Evaluation System has now transferred to the National Defense University. All associated records are covered under SORN DNDU 01 (September 21, 2010, 75 FR 57458). Therefore, the system of records notice can be deleted.

[FR Doc. 2012–11420 Filed 5–10–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Public Meetings for the Draft Environmental Impact Statement/ Overseas Environmental Impact Statement for Navy Atlantic Fleet Training and Testing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969 and regulations implemented by the Council on Environmental Quality (40 Code of Federal Regulations parts 1500–1508), and Presidential Executive Order (EO) 12114, the Department of the Navy (DoN) has prepared and filed with the U.S. Environmental Protection Agency a Draft Environmental Impact Statement (EIS)/Overseas EIS (OEIS). The Draft EIS/OEIS evaluates the potential environmental effects associated with military readiness training and research, development, test and evaluation activities (training and testing) conducted within the Atlantic Fleet Training and Testing (AFTT) Study Area. The National Marine Fisheries Service (NMFS) is a cooperating agency for the EIS/OEIS.

The Study Area is in the western Atlantic Ocean and encompasses the waters off the east coast of North America and the Gulf of Mexico. The Study Area covers approximately 2.6 million square nautical miles of ocean area, and includes designated DoN operating areas and special use airspace. The following DoN testing ranges and range complexes fall within the Study Area: Northeast Range Complexes; Naval Undersea Warfare Center Division, Newport Testing Range; Virginia Capes Range Complex; Navy Cherry Point Range Complex; Jacksonville Range Complex; South Florida Ocean Measurement Facility Testing Range; Undersea Warfare Training Range; Key West Range Complex; Naval Surface Warfare Center, Panama City Division Testing Range; and Gulf of Mexico Range Complex. The Study Area only includes the at-sea components of these range complexes and testing ranges, with the exception of the Narragansett Bay, lower Chesapeake Bay, St. Andrew Bay. Navy pierside locations and port transit channels where sonar maintenance and testing occur, and bays and civilian ports where training occurs are also included in the Study Area as indicated on the map. The remaining inland waters and land-based portions of the range complexes are not a part of the Study Area and will be or already have been addressed under separate environmental planning documentation.

With the filing of the Draft EIS/OEIS, the DoN is initiating a 60-day public comment period beginning on May 11, 2012 and ending on July 10, 2012. During this period, the DoN will conduct five public meetings to receive oral and written comments on the Draft EIS/OEIS. This notice announces the dates and locations of the public meetings and provides supplementary information about the environmental planning effort.

DATES AND ADDRESSES: Public information and comment meetings will be held at each of the locations listed below between 4:00 p.m. and 8:00 p.m. The meetings will provide individuals with information on the Draft EIS/OEIS in an open house format. DoN and NMFS representatives at informational poster stations will be available during the public meetings to clarify information related to the Draft EIS/OEIS.

The public meetings will be held between 4 p.m. and 8 p.m. on the following dates and at the following locations:

1. May 30, 2012 (Wednesday) at Hotel Providence, 139 Mathewson Street, Providence, RI;

2. June 5, 2012 (Tuesday) at Prime F. Osborn III Convention Center, 1000 Water Street, Jacksonville, FL;

3. June 6, 2012 (Wednesday) Hilton Garden Inn Panama City, 1101 North Highway 231, Panama City, FL;

4. June 11, 2012 (Monday) at Virginia Beach Convention Center, 1000 19th Street, Virginia Beach, VA;

5. June 12, 2012 (Tuesday) at Hampton Inn and Suites Swansboro, 215 Old Hammock Road, Swansboro, NC.

Federal, State and local agencies and officials, and interested groups and individuals are encouraged to provide comments in person at any of the public meetings or in writing anytime during the public comment period. At the public meetings, attendees will be able to submit comments orally using a voice recorder or in writing. Equal weight will be given to oral and written statements. Comments may also be submitted via the U.S. Postal Service to Naval Facilities Engineering Command Atlantic, Attn Code EV22 (AFTT EIS Project Managers), 6506 Hampton Boulevard, Norfolk, VA 23508–1278 or electronically via the project Web site (*http://www.AFTTEIS.com*). All statements, oral or written, submitted during the public review period will become part of the public record on the Draft EIS/OEIS and will be responded to in the Final EIS/OEIS. All written comments must be post marked or received by July 10, 2012, to ensure they become part of the official record.

FOR FURTHER INFORMATION CONTACT: Naval Facilities Engineering Command Atlantic, Attn Code EV22 (AFTT EIS Project Managers), 6506 Hampton Boulevard, Norfolk, VA 23508–1278.

SUPPLEMENTARY INFORMATION: A Notice of Intent (NOI) to prepare this DEIS/OEIS was published in the **Federal Register** on July 15, 2010, (75 FR 41163).

The DoN's Proposed Action is to conduct training and testing activities—which may include the use of active sonar and explosives—primarily within existing range complexes and testing ranges along the east coast of the United States, the Gulf of Mexico, Navy pierside locations, port transit channels, and the lower Chesapeake Bay. The purpose of the Proposed Action is to conduct training and testing activities to ensure that the DoN meets its mission to maintain, train, and equip combat-ready U.S. naval forces capable of winning wars, deterring aggression, and maintaining freedom of the seas. This Draft EIS/OEIS will also support the renewal of federal regulatory permits and authorizations for current training and testing activities and to propose future training and testing activities requiring environmental analysis.

The Draft EIS/OEIS evaluates the potential environmental impacts of three alternatives, including the No Action Alternative and two action alternatives. The No Action Alternative continues baseline training and testing activities, as defined by existing DoN environmental planning documents.

Alternatives 1 and 2 analyze adjustments to Study Area boundaries and the location, type, and level of training and testing activities necessary to support current and planned DoN training and testing requirements through 2019. The analysis addresses force structure changes, including those resulting from the development, testing, and ultimate introduction of new vessels, aircraft and weapons systems into the fleet.

No significant adverse impacts are identified for any resource area in any geographic location within the Study Area that cannot be mitigated. Additionally, due to the exposure of marine mammals to underwater sound, NMFS has received an application from DoN for a Marine Mammal Protection Act Letter of Authorization and governing regulations to authorize incidental take of marine mammals that may result from the implementation of the activities analyzed in the Draft EIS/OEIS. In accordance with Section 7 of the Endangered Species Act, the DoN is consulting with NMFS and U.S. Fish and Wildlife Service, as appropriate, for potential impacts to federally listed species. In accordance with the Magnuson-Stevens Fishery Conservation and Management Act, the DoN is consulting with NMFS on federally managed species and their essential fish habitat. The DoN will initiate consultation under the National Historic Preservation Act regarding impacts to historic properties, and will comply with other applicable laws and regulations.

The Draft EIS/OEIS was distributed to Federal, State, and local agencies, elected officials, and other interested individuals and organizations. Copies of the Draft EIS/OEIS are available for public review at the following libraries:

1. Anne Arundel County Public Library, Annapolis Area Branch, 1410 West Street, Annapolis, MD 21401.
2. Bay County Public Library, 898 West 11th Street, Panama City, FL 32401.
3. Ben May Main Library, 701 Government Street, Mobile, AL 36602.
4. Boston Public Library, Central Library, 700 Boylston Street, Boston, MA 02116.
5. Camden County Public Library, 1410 Highway 40 E, Kingsland, GA 31548.
6. Carteret County Public Library, 1702 Live Oak Street, Suite 100, Beaufort, NC 28516.
7. Charleston County Public Library, Main Library, 68 Calhoun Street, Charleston, SC 29401.
8. Corpus Christi Public Library, La Retama Library, 805 Comanche, Corpus Christi, TX 78401.
9. East Bank Regional Library, 4747 West Napoleon Avenue, Metairie, LA 70001.
10. Hatteras Library, 57709 Highway 12, Hatteras, NC 27943.
11. Havelock-Craven County Public Library, 301 Cunningham Boulevard, Havelock, NC 28532.
12. Houston Public Library, 500 McKinney Street, Houston, TX 77002.
13. Jacksonville Public Library, Main Library, 303 North Laura Street, Jacksonville, FL 32202.
14. Kill Devil Hills Branch Library, Main Library, 400 Mustian Street, Kill Devil Hills, NC 27948.
15. Meridian-Lauderdale County Public Library, 2517 7th Street, Meridian, MS 39301.
16. New Hanover County Public Library, 201 Chestnut Street, Wilmington, NC 28401.
17. New Orleans Public Library, Main Library, 219 Loyola Avenue, New Orleans, LA 70112.
18. Mary D. Pretlow Anchor Branch Library, 111 West Ocean View Avenue, Norfolk, VA 23503.
19. Onslow County Public Library, 58 Doris Avenue East, Jacksonville, NC 28540.
20. Portland Public Library, 5 Monument Square, Portland, ME 04101.
21. Providence Public Library, 150 Empire Street, Providence, RI 02903.
22. Public Library of New London, 63 Huntington Street, New London, CT 06320.
23. Southmost Branch Library, 4320 Southmost Boulevard, Brownsville, TX 78521.
24. Walton County Coastal Branch Library, 437 Greenway Trail, Santa Rosa Beach, FL 32459.
25. Webb Memorial Library and Civic Center, 812 Evans Street, Morehead City, NC 28557.
26. West Florida Public Library, Main Library, 200 West Gregory Street, Pensacola, FL 32502.
27. West Florida Public Library, Southwest Branch, 12248 Gulf Beach Highway, Pensacola, FL 32507.
28. West Palm Beach Public Library, 411 Clematis Street, West Palm Beach, FL 33401.

Copies of the AFTT Draft EIS/OEIS are available for electronic viewing or download at *http://www.AFTTEIS.com*. A paper copy of the Executive Summary or a single compact disc of the Draft EIS/OEIS will be made available upon written request by contacting: Naval Facilities Engineering Command Atlantic, Attn Code EV22 (AFTT EIS Project Managers), 6506 Hampton Boulevard, Norfolk, VA 23508–1278.

Dated: May 4, 2012.

J.M. Beal,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2012–11410 Filed 5–10–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Public Meetings for the Draft Environmental Impact Statement/Overseas Environmental Impact Statement for Navy Hawaii-Southern California Training and Testing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, and regulations implemented by the Council on Environmental Quality regulations (40 Code of Federal Regulations parts 1500–1508), and Presidential Executive Order 12114, the Department of the Navy (DoN) has prepared and filed with the U.S. Environmental Protection Agency a Draft Environmental Impact Statement (EIS)/Overseas EIS (OEIS). The Draft EIS/OEIS evaluates the potential environmental effects associated with military readiness training and research, development, test and evaluation activities (training and testing) conducted within the Hawaii-Southern California Training and Testing (HSTT) Study Area. The National Marine Fisheries Service (NMFS) is a Cooperating Agency for the EIS/OEIS.

The HSTT Study Area is comprised of established operating and warning areas across the north-central Pacific Ocean, from Southern California west to Hawaii and the International Date Line. The Study Area combines the at-sea portions of the Hawaii Range Complex; the Southern California Range Complex; the Silver Strand Training Complex; transit corridors on the high seas that are not part of the range complexes where training and sonar testing may occur during vessel transit between the Hawaii Range Complex and the Southern California Range Complex; and Navy pierside locations where sonar maintenance and testing activities occurs. The HSTT Study Area includes only the at-sea components of the range complexes and testing ranges. The land-based portions of the range complexes are not a part of the Study Area and will be or already have been addressed under separate DoN environmental planning documentation.

With the filing of the Draft EIS/OEIS, the DoN is initiating a 60-day public comment period, beginning on May 11, 2012 and ending on July 10, 2012. During this period the DoN will conduct five public meetings to receive oral and written comments on the Draft EIS/OEIS. This notice announces the dates and locations of the public meetings and provides supplementary information about the environmental planning effort.

DATES AND ADDRESSES: Public information and comment meetings will be held at each of the locations listed below between 5:00 p.m. and 8:00 p.m. The meetings will provide individuals with information on the Draft EIS/OEIS in an open house format. DoN and NMFS representatives at informational poster stations will be available during the public meetings to clarify information related to the Draft EIS/OEIS.

The public meetings will be held between 5:00 p.m. and 8:00 p.m. on the following dates and at the following locations:

1. June 12, 2012 (Tuesday) at the Wilcox Elementary School Cafeteria, 4319 Hardy Street, Lihue, HI.
2. June 13, 2012 (Wednesday at Maui Waena Intermediate School Cafeteria, 795 Onehee Avenue, Kahului, HI.
3. June 14, 2012 (Thursday) at East Hawaii Cultural Center, 141 Kalakaua Street, Hilo, HI.
4. June 15, 2012 (Friday) at McKinley High School Cafeteria, 1039 South King Street, Honolulu, HI.
5. June 20, 2012 (Wednesday) at Marina Village Conference Center, Starboard Room, 1936 Quivira Way, San Diego, CA.

Federal, State and local agencies and officials, interested groups and individuals are encouraged to provide oral comments in person at any of the public meetings or in writing anytime during the public comment period. Oral testimony from the public will be recorded by a court reporter. In the interest of available time, and to ensure all who wish to give an oral statement to the court reporter have the opportunity to do so, each speaker's comments will be limited to three (3) minutes, which may be extended if meeting attendance permits. Comments may also be submitted via the U.S. Postal Service to Naval Facilities Engineering Command, Southwest, Attention: HSTT EIS/OEIS Project Manager—EV21.CS; 1220 Pacific Highway, Building 1, Floor 3, San Diego, CA 92132–5190 or electronically via the project Web site (*http://www.HSTTEIS.com*). All statements, oral or written, submitted during the public review period will become part of the public record on the Draft EIS/OEIS and will be responded to in the Final EIS/OEIS. Equal weight will be given to oral and written statements. All public comments must be postmarked or received by July 10, 2012 to ensure they become part of the official record.

FOR FURTHER INFORMATION CONTACT: Naval Facilities Engineering Command, Southwest, Attention: HSTT EIS/OEIS Project Manager—EV21.CS; 1220 Pacific Highway, Building 1, Floor 3, San Diego, CA 92132–5190.

SUPPLEMENTARY INFORMATION: A Notice of Intent to prepare this Draft EIS/OEIS was published in the **Federal Register** on July 15, 2010 (75 FR 41162).

The DoN's Proposed Action is to conduct training and testing activities—which may include the use of active Sound Navigation and Ranging (sonar) and explosives—primarily within existing range complexes and testing ranges throughout the in-water areas around the Hawaiian Islands and off the coast of Southern California, Navy pierside locations, and the ocean transit corridor between Hawaii and Southern California. The purpose of the Proposed Action is to conduct training and testing activities to ensure that the DoN accomplishes its mission to maintain, train, and equip combat-ready U.S. naval forces capable of winning wars, deterring aggression, and maintaining freedom of the seas. This Draft EIS/OEIS will also support the renewal of federal regulatory permits and authorizations for current training and testing activities and to propose future training and testing activities requiring environmental analysis.

The Draft EIS/OEIS evaluates the potential environmental impacts of three alternatives, including the No Action Alternative and two action alternatives. The No Action Alternative continues baseline training and testing activities, as defined by existing DoN environmental planning documents. Alternatives 1 and 2 analyze adjustments to Study Area boundaries and the location, type, and level of training and testing activities necessary to support current and planned DoN training and testing requirements through 2019. The analysis addresses force structure changes, including those resulting from the development, testing, and ultimate introduction of new vessels, aircraft and weapons systems into the fleet.

No significant adverse impacts are identified for any resource area in any geographic location within the Study Area that cannot be mitigated. Additionally, due to the exposure of marine mammals to underwater sound, NMFS has received an application from DoN for a Marine Mammal Protection Act Letter of Authorization and governing regulations to authorize incidental take of marine mammals that may result from the implementation of the activities analyzed in the Draft EIS/OEIS. In accordance with Section 7 of the Endangered Species Act, the DoN is consulting with NMFS and U.S. Fish and Wildlife Service, as appropriate, for potential impacts to federally listed species. In accordance with the Magnuson-Stevens Fishery Conservation and Management Act, the DoN is consulting with NMFS on Federally managed species and their essential fish habitat.

The Draft EIS/OEIS was distributed to Federal, State and local agencies, elected officials, as well as other interested individuals and organizations. Copies of the Draft EIS/OEIS are also available for public review at the following libraries:

1. Lihue Public Library, 4344 Hardy Street, Lihue, HI 96766.
2. Wailuku Public Library, 251 High Street, Wailuku, HI 96793.
3. Hilo Public Library, 300 Waianuenue Avenue, Hilo, HI 96720.
4. Kailua-Kona Public Library, 75–138 Hualalai Road, Kailua-Kona, HI 96740.
5. Hawaii State Library, Hawaii and Pacific Section Document Unit, 478 South King Street, Honolulu, HI 96813.
6. San Diego Central Library, 820 E Street, San Diego, CA 92101.
7. Long Beach Main Library, 101 Pacific Avenue, Long Beach, CA 90822.

In addition, copies of the HSTT Draft EIS/OEIS are available for electronic viewing or download at *http://www.HSTTEIS.com.* A paper copy of the Executive Summary or a single compact disc of the Draft EIS/OEIS will be made available upon written request by contacting: Naval Facilities Engineering Command, Southwest, Attention: HSTT EIS/OEIS Project Manager—EV21.CS; 1220 Pacific Highway, Building 1, Floor 3, San Diego, CA 92132–5190.

Dated: May 7, 2012.

J.M. Beal,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2012–11387 Filed 5–10–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2012–0007]

Privacy Act of 1974; System of Records

AGENCY: Department of the Navy, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Department of the Navy proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on June 11, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Patterson, Department of the Navy, DNS–36, 2000 Navy Pentagon, Washington, DC 20350–2000 or call at (202) 685–6545.

SUPPLEMENTARY INFORMATION: The Department of the Navy notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on May 3, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: May 8, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

NM–05724–1

SYSTEM NAME:

Fleet Hometown News System (FHNS) Records (December 12, 2008, 73 FR 75692).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Active-duty and reserve Navy, Marine Corps, Coast Guard, Army, and Air Force personnel and government civilian personnel.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Information submitted includes: full name, signature, rank, gender, marital status, date entered service, branch of service, duty status, Command mailing address, date reported, duty to which assigned/job title, spouse's first name, father's name and address, mother's name and address, father-in-law's name and address, mother-in-law's name and address, high school and college/university complete names, graduation dates, degrees received, city, state, and zip codes, and promotions, awards, photographs and significant career events.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''5 U.S.C. 301, Departmental Regulations; 10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; function; composition; 14 U.S.C. 93, Commandant, General Powers; 10 U.S.C. 8013, Secretary of the Air Force; 10 U.S.C. 8034, Vice Chief of Staff; 10 U.S.C. 3013 Secretary of the Army; and SECNAVINST 5724.3A, Fleet Hometown News Program Policy and Procedures.''

PURPOSE(S):

Delete entry and replace with ''Information is collected and maintained to generate public awareness of the accomplishments of Navy, Marine Corps, Coast Guard, Army, Air Force, and government civilian personnel by distributing news releases and photographs to the hometown news media of individual service members or employees. Hometown news media include, but are not limited to, newspapers, radio and television stations, and college/university alumni publications throughout the United States and its territories and their respective Web sites. Release of this information is done with the individual's full cooperation and written consent.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USES AND THE PURPOSES OF SUCH USES:

Delete entry and replace with ''In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the news media in individual service member's or employee's hometown for publication by local news media to recognize the achievements of service members. Release of this information is done with the individual's full cooperation and written consent.

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.''

* * * * *

RETRIEVABILITY:

Delete entry and replace with ''By individuals name.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Fleet Hometown News System Manager, 9320 Third Avenue, Suite 100, Norfolk, VA 23511–2125.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Fleet Hometown News System Manager, 9420 Third Avenue, Suite 100, Norfolk, VA 23511–2125. Requests should contain the individual's full name and must be signed by the individual.

The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the Fleet Hometown News System Manager, 9420 Third Avenue, Suite 100, Norfolk, VA 23511–

2125. Requests should contain the individual's full name and must be signed by the individual.

The system manager may require an original signature or a notarized signature as a means of proving the identity of the individual requesting access to the records.''

* * * * *

[FR Doc. 2012–11451 Filed 5–10–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Notice of Submission for OMB Review; Federal Student Aid; Lender Application Process (LAP)

SUMMARY: The Lender's Application Process is submitted by lenders who are eligible for reimbursement of interest and special allowance, as well as Federal Insured Student Loan claims payment, under the Federal Family Education Loan Program.

DATES: Interested persons are invited to submit comments on or before June 11, 2012.

ADDRESSES: Written comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 04819. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Lender Application Process (LAP).

OMB Control Number: 1845–0032.

Type of Review: Extension.

Total Estimated Number of Annual Responses: 30.

Total Estimated Number of Annual Burden Hours: 5.

Abstract: The information from the Lender Application Process will be used by the U.S. Department of Education to update Lender Identification Numbers, lender's names, and addresses with nine-digit zip codes and other pertinent information.

Dated: May 7, 2012.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2012–11378 Filed 5–10–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Submission for OMB Review; Office of Special Education and Rehabilitative Services; Annual Protection and Advocacy for Assistive Technology (PAAT) Program Performance Report, Form RSA 661

SUMMARY: The Annual Protection and Advocacy for Assistive Technology (PAAT) Program Performance Report, Form RSA–661 is used to analyze and evaluate the PAAT Program administered by eligible systems in states. These systems provide services to eligible individuals with disabilities to assist in the acquisition, utilization, or maintenance of assistive technology devices or assistive technology services.

DATES: Interested persons are invited to submit comments on or before June 11, 2012.

ADDRESSES: Written comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 04820. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Annual Protection and Advocacy for Assistive Technology (PAAT) Program Performance Report, Form RSA 661.

OMB Control Number: 1820–0661.

Type of Review: Extension.

Total Estimated Number of Annual Responses: 57.

Total Estimated Number of Annual Burden Hours: 912.

Abstract: The Rehabilitative Services Administration (RSA) uses the form to meet specific data collection requirements of Section 5 of the Assistive Technology Act of 1998, as amended. PAAT programs must report annually using the form, which is due on or before December 30 each year. The Annual PAAT Performance Report has enabled RSA to furnish the President and Congress with data on the provision of protection and advocacy services and has helped to establish a sound basis for future funding requests. Data from the form has been used to evaluate the effectiveness of eligible systems within individual states in meeting annual priorities and objectives. These data also have been used to indicate trends in the provision of services from year to year.

Dated: May 7, 2012.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2012–11342 Filed 5–10–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Personnel Preparation in Special Education, Early Intervention, and Related Services

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information: Personnel Development To Improve Services and Results for Children With Disabilities—Personnel Preparation in Special Education, Early Intervention, and Related Services; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2012.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.325K.

DATES: *Applications Available:* May 11, 2012.

Deadline for Transmittal of Applications: June 25, 2012.

Deadline for Intergovernmental Review: August 24, 2012.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for highly qualified personnel—in special education, early intervention, related services, and regular education—to work with children, including infants and toddlers, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

Priorities: In accordance with 34 CFR 75.105(b)(2)(iv), this priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA)).

Absolute Priority: For FY 2012 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Personnel Preparation in Special Education, Early Intervention, and Related Services.

Background:

The purpose of the Personnel Preparation in Special Education, Early Intervention, and Related Services priority is to improve the quality and increase the number of personnel who are fully credentialed to serve children, including infants and toddlers, with disabilities—especially in areas of chronic personnel shortage—by supporting projects that prepare special education, early intervention, and related services personnel at the baccalaureate, master's, and specialist levels.

State demand for fully credentialed special education, early intervention, and related services personnel to serve infants, toddlers, and children with disabilities exceeds the available supply (Bruder, 2004a; Bruder, 2004b; McLeskey & Billingsley, 2008; and McLeskey, Tyler & Flippin, 2004). These shortages of fully credentialed personnel can negatively affect the quality of services provided to infants, toddlers, and children with disabilities and their families (McLeskey et al., 2004).

Personnel preparation programs that prepare personnel to enter the fields of special education, early intervention, and related services as fully credentialed personnel with the necessary competencies to use evidence-based practices are critical to overcome the personnel shortages in these fields. Federal support of these personnel preparation programs is needed to increase the supply of personnel with the necessary competencies to effectively serve infants, toddlers, and children with disabilities and their families.

Priority:

Except as provided for Focus Area D projects, to be eligible under this priority, an applicant must propose a project associated with a pre-existing personnel preparation program that will prepare and support scholars [1] to complete, within the project period of the grant, a degree, State certification, professional license, or State endorsement in special education, early intervention, or a related services field. Projects also can be associated with personnel preparation programs that (a) prepare individuals to be assistants in related services professions (e.g., physical therapist assistants, occupational therapist assistants), or educational interpreters; or (b) provide an alternate route to certification or that support dual certification (special education and regular education) for teachers. For purposes of this priority, the term ''personnel preparation program'' refers to the program with which the applicant's proposed project is associated.

To be considered for funding under the Personnel Preparation in Special Education, Early Intervention, and Related Services absolute priority, applicants must meet the application requirements contained in the priority. All projects funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority. These requirements are as follows:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how the proposed project will—

(1) Address national, State, or regional shortages of personnel who are fully credentialed to serve children with disabilities, ages birth through 21, including high-need children with disabilities,[2] by preparing special

[1] For the purposes of this priority, the term ''scholar'' means an individual who is pursuing a degree, license, endorsement, or certification related to special education, related services, or early intervention services and who receives scholarship assistance under section 662 of IDEA (see 34 CFR 304.3(g)).

[2] For the purpose of this priority, ''high-need children with disabilities'' refers to children (ages birth through 21, depending on the State) who are eligible for services under IDEA, and who may be further disadvantaged and at risk of educational

Continued

education, early intervention, or related services personnel at the baccalaureate, master's, and specialist levels. To address this requirement, the applicant must present—

(i) Data that demonstrate a national, State, or regional need for the personnel the applicant proposes to prepare; and

(ii) Data that demonstrate the effectiveness of the applicant's personnel preparation program in preparing personnel in special education, early intervention, or related services.[3] These data could include the average amount of time it takes program participants to complete the program; the percentage of program graduates finding employment related to their preparation within one year of graduation; or the percentage of program graduates who maintain employment for three or more years in the area for which they were prepared and who are fully qualified under IDEA. When providing the percentages in response to this paragraph, the applicant must also provide the denominator or total number of program participants or program graduates for each percentage.

(2) Increase the number of personnel who demonstrate the competencies needed to provide high-quality instruction, evidence-based interventions, and services for children with disabilities, ages birth through 21, including high-need children with disabilities, that result in improvements in learning and developmental outcomes (e.g., academic, social, emotional, behavioral) and growth toward learning and developmental outcomes. To address this requirement, the applicant must—

(i) Identify the competencies[4] that special education, early intervention, or related services personnel need in order to provide high-quality instruction, interventions, and services that will lead to improved outcomes of children with disabilities, ages birth through 21, including high-need children with disabilities; and

(ii) Provide the conceptual framework of the personnel preparation program, including any empirical support, that will promote the acquisition of the identified competencies (see paragraph (a)(2)(i) of this priority) needed by special education, early intervention, or related services personnel, and how these competencies relate to the proposed project.

(b) Demonstrate, in the narrative section of the application under ''Quality of Project Services,'' how the proposed project—

(1) Will use strategies to recruit and retain high-quality scholars and ensure equal access and treatment for eligible project participants who are members of groups who have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe—

(i) The selection criteria that it will use to identify high-quality applicants for enrollment in the proposed project;

(ii) The recruitment strategies that it will use to attract high-quality applicants, including any specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, for enrollment in the proposed project; and

(iii) The approach, including mentoring and monitoring, that will be used to support scholars to complete the personnel preparation program.

(2) Reflects current research and evidence-based practices and is designed to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how the proposed project will—

(i) Incorporate current research and evidence-based practices that improve outcomes for children with disabilities (including relevant research citations) into the project's required coursework and clinical experiences; and

(ii) Use current research and evidence-based professional development practices for adult learners to instruct scholars.

(3) Is of sufficient quality, intensity, and duration to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how—

(i) The components of the proposed project (e.g., coursework, clinical experiences, or internships) will support scholars' acquisition and enhancement of the identified competencies;

(ii) The components of the proposed project (e.g., coursework, clinical experiences, internships) will be integrated to allow scholars to use their content knowledge in clinical practice, and how scholars will be provided with ongoing guidance and feedback;

(iii) The proposed project will provide ongoing induction opportunities and support to program graduates.

(4) Will collaborate with appropriate partners, including—

(i) High-need LEAs;[5] high-poverty schools;[6] low-performing schools including persistently lowest-achieving schools;[7] priority schools (in the case of States that have received the Department's approval of a request for

failure because they: (1) Are living in poverty, (2) are far below grade level, (3) are at risk of not graduating with a regular high school diploma on time, (4) are homeless, (5) are in foster care, (6) have been incarcerated, (7) are English learners, (8) are pregnant or parenting teenagers, (9) are new immigrants, (10) are migrant, or (11) are not on track to being college- or career-ready by graduation.

[3] Data provided in response to this requirement must be no older than five years from the start date of the project proposed in the application.

[4] For the purpose of this priority, the term ''competencies'' means what a person knows and can do: The knowledge, skills and dispositions necessary to effectively function in a role (National Professional Development Center on Inclusion, 2011).

[5] For the purposes of this priority, the term ''high-need LEA'' means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line.

[6] For the purposes of this priority, the term ''high-poverty school'' means a school in which at least 50 percent of students are eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act or in which at least 50 percent of students are from low-income families as determined using one of the criteria specified under section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA). For middle and high schools, eligibility may be calculated on the basis of comparable data from feeder schools. Eligibility as a high-poverty school under this definition is determined on the basis of the most currently available data (*www2.ed.gov/legislation/FedRegister/other/2010-4/121510b.html*).

[7] For the purposes of this priority, the term ''persistently lowest-achieving schools'' means, as determined by the State—

(a)(1) Any Title I school in improvement, corrective action, or restructuring that—

(i) Is among the lowest-achieving five percent of Title I schools in improvement, corrective action, or restructuring or the lowest-achieving five Title I schools in improvement, corrective action, or restructuring in the State, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years; and

(2) Any secondary school that is eligible for, but does not receive, Title I funds that—

(i) Is among the lowest-achieving five percent of secondary schools or the lowest-achieving five secondary schools in the State that are eligible for, but do not receive, Title I funds, whichever number of schools is greater; or

(ii) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years.

(b) To identify the lowest-achieving schools, a State must take into account both—

(i) The academic achievement of the ''all students'' group in a school in terms of proficiency on the State's assessments under section 1111(b)(3) of the ESEA in reading/language arts and mathematics combined; and

(ii) The school's lack of progress on those assessments over a number of years in the ''all students'' group.

For the purposes of this priority, the Department considers schools that are identified as Tier I or Tier II schools under the School Improvement Grants Program (see 75 FR 66363) as part of a State's approved FY 2009 or FY 2010 applications to be persistently lowest-achieving schools. A list of these Tier I and Tier II schools can be found on the Department's Web site at *http://www2.ed.gov/programs/sif/index.html*.

Elementary and Secondary Education Act of 1965, as amended (ESEA) flexibility),[8] and publicly-funded preschool programs, including Head Start programs and programs serving children eligible for services under IDEA Part C and Part B Section 619, that are located within the geographic boundaries of a high-need LEA. The purpose of these partnerships is to provide clinical practice for scholars aimed at developing the identified competencies; and

(ii) Other programs on campus or at partnering universities for the purpose of sharing resources, supporting program development and delivery, and addressing personnel shortages.

(5) Will use technology, as appropriate, to promote scholar learning, enhance the efficiency of the project, collaborate with partners, and facilitate ongoing mentoring and support for scholars.

(c) Include, in the narrative section of the application under ''Quality of Project Evaluation,'' how—

(1) The proposed project will use comprehensive and appropriate methodologies to evaluate the effectiveness of the project, including the effectiveness of project processes and outcomes;

(2) The proposed project will collect and analyze data related to specific and measurable goals, objectives, and outcomes of the project. To address this requirement, the applicant must describe—

(i) How scholar competencies and other project processes and outcomes will be measured for formative evaluation purposes, including proposed instruments, data collection methods, and possible analyses; and

(ii) How data on the quality of services provided by proposed project graduates, including data on the learning and developmental outcomes (e.g., academic, social, emotional, behavioral) and growth toward learning and developmental outcomes of the children with disabilities they serve, will be collected and analyzed;

Note: Following the completion of the project period, grantees are encouraged—but not required—to engage in ongoing data collection activities.

(3) The methods of evaluation will produce quantitative and qualitative data for objective performance measures that are related to the outcomes of the proposed project; and

(4) The methods of evaluation will provide performance feedback and allow for periodic assessment of progress towards meeting the project outcomes. To address this requirement, the applicant must describe how—-

(i) Findings from the evaluation will be used as a basis for improving the proposed project to prepare special education, early intervention, or related services personnel to provide high-quality interventions and services to improve outcomes of children with disabilities; and

(ii) The proposed project will report evaluation results to the Office of Special Education Programs (OSEP) in the annual and final performance reports.

(d) Demonstrate, in the narrative under ''Project Assurances,'' or appendices, as applicable, that the following program requirements are met. The applicant must—-

(1) Include, in the application appendix, syllabi for all required coursework of the proposed project, including syllabi for new or proposed courses.

(2) Ensure that all scholars who enroll in the proposed project can graduate by the end of the grant's project period.

(3) Ensure that the project will meet the statutory requirements in section 662(e) through 662(h) of IDEA.

(4) Ensure that at least 65 percent of the total requested budget over the five years will be used for scholar support.

(5) Ensure that the institution of higher education (IHE) will not require scholars to work (e.g., as graduate assistants) as a condition of receiving support (e.g., tuition, stipends, books) from the proposed project unless the work is specifically required to advance scholars' competencies or complete other requirements in their personnel preparation program. Please note that this prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA.

(6) Ensure that the budget includes attendance of the project director at a three-day Project Directors' meeting in Washington, DC, during each year of the project.

(7) Ensure that if the proposed project maintains a Web site, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility.

(8) Ensure that the Project Director will submit annual data on each scholar who receives grant support. Applicants are encouraged to visit the Personnel Development Program Scholar Data Report Web site at: *http://oseppdp.ed.gov* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590).

Focus Areas:

Within this absolute priority, the Secretary intends to support projects under the following four focus areas: (A) Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities; (B) Preparing Personnel to Serve School-Age Children with Low-Incidence Disabilities; (C) Preparing Personnel to Provide Related Services to Children, Including Infants and Toddlers, with Disabilities; and (D) Preparing Personnel in Minority Institutions of Higher Education to Serve Children, Including Infants and Toddlers, with Disabilities. Interdisciplinary projects are encouraged to apply under Focus Area A, B, C, or, D. Interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines.

Note: Applicants must identify the specific focus area (i.e., A, B, C, or D) under which they are applying as part of the competition title on the application cover sheet (SF form 424, line 4). Applicants may not submit the same proposal under more than one focus area.

Focus Area A: Preparing Personnel To Serve Infants, Toddlers, and Preschool-Age Children With Disabilities. OSEP intends to fund nine awards under this focus area. For the purpose of Focus Area A, early intervention personnel are those who are prepared to provide services to infants and toddlers with disabilities ages birth to three, and early childhood personnel are those who are prepared to provide services to children with disabilities ages three through five (in States where the age range is other than ages three through five, we will defer to the State's certification for early childhood). In States where certification in early intervention is combined with certification in early childhood, applicants may propose a combined early intervention and early childhood personnel preparation project under this focus area. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines

[8] For the purposes of this priority, the term ''priority school'' means a school that has been identified by the State as a priority school pursuant to the State's approved request for ESEA flexibility.

for early intervention providers or early childhood special educators, and related services personnel to serve infants, toddlers, and preschool-age children with disabilities. Projects preparing only related services personnel to serve infants, toddlers, and preschool-age children with disabilities are not eligible under this focus area (see Focus Area C).

Focus Area B: Preparing Personnel To Serve School-Age Children With Low-Incidence Disabilities. OSEP intends to fund 11 awards under this focus area. For the purpose of Focus Area B, personnel who serve children with low-incidence disabilities are special education personnel prepared to serve school-age children with low-incidence disabilities including visual impairments, hearing impairments, simultaneous visual and hearing impairments, significant intellectual disabilities, orthopedic impairments, autism, and traumatic brain injury. Programs preparing special education personnel to provide services to children with visual impairments or blindness that can be appropriately provided in braille must prepare those individuals to provide those services in braille. Projects preparing educational interpreters are eligible under this focus area. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines for low-incidence and related services personnel to serve school-aged children with low incidence disabilities. Projects preparing early intervention or preschool personnel are not eligible under this focus area (see Focus Area A).

Focus Area C: Preparing Personnel To Provide Related Services to Children, Including Infants and Toddlers, With Disabilities. OSEP intends to fund nine awards under this focus area. Programs preparing related services personnel to serve children, including infants and toddlers, with disabilities are eligible within Focus Area C. For the purpose of this focus area, related services include, but are not limited to, psychological services, physical therapy (including therapy provided by personnel prepared at the Doctor of Physical Therapy (DPT) level), adapted physical education, occupational therapy, therapeutic recreation, social work services, counseling services, audiology services (including services provided by personnel prepared at the Doctor of Audiology (AudD) level), and speech and language services. Preparation programs in States where personnel prepared to serve children with speech and language impairments are considered to be special educators are eligible under this focus area. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines for related services personnel who serve children, including infants and toddlers, with disabilities. Projects preparing educational interpreters are not eligible under this focus area (see Focus Area B).

Focus Area D: Preparing Personnel in Minority Institutions of Higher Education To Serve Children, Including Infants and Toddlers, With Disabilities. OSEP intends to fund 10 awards under this focus area. Programs in minority IHEs are eligible under Focus Area D if they prepare one of the following: (a) Personnel to serve infants, toddlers, and preschool-age children with disabilities; (b) personnel to serve school-age children with low-incidence disabilities; or (c) personnel to provide related services to children, including infants and toddlers, with disabilities. Minority IHEs include IHEs with a minority enrollment of 25 percent or more, which may include Historically Black Colleges and Universities, Tribal Colleges, and Predominantly Hispanic Serving Colleges and Universities. We encourage interdisciplinary projects under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through coursework and clinical experiences shared across disciplines for: (a) Early intervention providers or early childhood special educators and related services personnel who serve infants, toddlers, and preschool-age children with disabilities; (b) low-incidence and related services personnel who serve school-age children with low-incidence disabilities; or (c) related services personnel who serve children, including infants and toddlers, with disabilities. Programs in minority IHEs preparing personnel in Focus Area A, B, or C are eligible within Focus Area D. Programs preparing high-incidence special education personnel are not eligible under this priority (for the purpose of this priority, ''high-incidence disabilities'' refers to learning disabilities, emotional disturbance, or intellectual disabilities).

Note: A project funded under Focus Area D may budget for less than 65 percent, the required percentage, for scholar support if the applicant can provide sufficient justification for any designation less than this required percentage. Sufficient justification for proposing less than 65 percent of the budget for scholar support would include support for activities such as program development, program expansion, or the addition of a new area of emphasis. Some examples of projects that may be eligible to designate less than 65 percent of their budget for scholar support include the following:

(1) A project that is proposing to develop and deliver a newly established personnel preparation program or add a new area of emphasis may request up to a year of funding for program development (e.g., hiring of a new faculty member or consultant to assist in course development, providing professional development and training for faculty). In the initial project year, scholar support would not be required. The project must demonstrate that the newly established program or area of emphasis is approved and ready for implementation in order to receive continuation funds in year two.

(2) A project that is proposing to expand or enhance an existing program may request funding for capacity building (e.g., hiring of a clinical practice supervisor, providing professional development and training for faculty), or purchasing needed resources (e.g., additional teaching supplies or specialized equipment to enhance instruction).

Note: Applicants proposing projects to develop, expand, or add a new area of emphasis to special education or related services programs must provide, in their applications, information on how these new areas will be sustained once Federal funding ends.

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that meet the following priority. For FY 2012 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority.

Competitive Preference Priority 1: Under 34 CFR 75.105(c)(2)(i) we award 5 points to an application that meets this priority.

This priority is:

In Focus Area D, applicants that document that they are IHEs with minority enrollment of 50 percent or more.

References

Bruder, M.B. (December, 2004a). *The National Landscape of Early Intervention in Personnel Preparation Standards under Part C of the Individuals with Disabilities Education Act (IDEA).* A.J. Pappanikou Center for Excellence in Developmental Disabilities, Farmington, CT. Available at: *http://www.uconnucedd.org/projects/per_prep/resources.html.*

Bruder, M.B. (December, 2004b). *The National Landscape of Early Intervention and Early Childhood Special Education: 619 Data Report.* A.J. Pappanikou Center

for Excellence in Developmental Disabilities, Farmington, CT. Available at: *http://www.uconnucedd.org/projects/per_prep/resources.html.*

McLeskey, J. & Billingsley, B. (2008). How does the quality and stability of the teaching force influence the research-to-practice gap? *Remedial and Special Education, 29*(5), 293–305.

McLeskey, J., Tyler, N., & Flippin, S.S. (2004). The supply and demand for special education teachers: A review of research regarding the chronic shortage of special education teachers. *Journal of Special Education, 38*(1), 5–21.

National Professional Development Center on Inclusion. (August, 2011). *Competencies for early childhood educators in the context of inclusion: Issues and guidance for states.* Chapel Hill, NC: The University of North Carolina, FPG Child Development Institute, Authors.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The regulations for this program in 34 CFR part 304.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $9,750,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2013 from the list of unfunded applicants from this competition.

Estimated Range of Awards: See chart.

Estimated Average Size of Awards: See chart.

Maximum Award: See chart.

Estimated Number of Awards: See chart.

Project Period: See chart.

PERSONNEL DEVELOPMENT TO IMPROVE SERVICES AND RESULTS FOR CHILDREN WITH DISABILITIES (84.325K) APPLICATION NOTICE FOR FISCAL YEAR 2012

CFDA number and name	Applications available	Deadline for transmittal of applications	Deadline for intergovern-mental review	Estimated range of awards	Estimated average size of awards	Maximum award (budget period of 12 months)	Estimated number of awards	Project period	Contact person
84.325K Personnel Preparation in Special Education, Early Intervention, and Related Services.	May 11, 2012	June 25, 2012	August 24, 2012.						
Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool Age Children with Disabilities.	.....	.....	.....	$225,000–$250,000	$237,500	* $250,000	9	Up to 60 mos.	Maryann McDermott 202–245–7439 *maryann.mcdermott@ed.gov* PCP, Room 4062.
Focus Area B: Preparing Personnel to Serve School-Age Children with Low-Incidence Disabilities.	.....	.....	.....	225,000–250,000	237,500	* 250,000	11	Up to 60 mos.	Maryann McDermott, 202–245–7439, *maryann.mcdermott@ed.gov,* PCP, Room 4062.
Focus Area C: Preparing Personnel to Provide Related Services to Children, Including Infants and Toddlers, with Disabilities.	.....	.....	.....	225,000–250,000	237,500	* 250,000	9	Up to 60 mos.	Sarah Allen, 202–245–7875, *sarah.allen@ed.gov,* PCP, Room 4105.
Focus Area D: Preparing Personnel in Minority Institutions of Higher Education to Serve Children, Including Infants and Toddlers, with Disabilities.	.....	.....	.....	225,000–250,000	237,500	* 250,000	10	Up to 60 mos.	Dawn Ellis, 202–245–6417, *dawn.ellis@ed.gov,* PCP, Room 4092.

* We will reject any application that proposes a budget exceeding the maximum award for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Note: The Department is not bound by any estimates in this notice.

III. Eligibility Information

1. *Eligible Applicants:* Institutions of higher education (IHEs).

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other: General Requirements*—(a) The projects funded under this program must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant and grant recipient funded under this program must involve individuals with disabilities or parents of individuals with disabilities ages birth through 26 in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs).

To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.*

To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.325K.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition. Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to the equivalent of no more than 50 pages using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, the references, or the letters of support. However, you must include all of the application narrative in Part III.

We will reject your application if you exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: May 11, 2012.

Deadline for Transmittal of Applications: June 25, 2012.

Applications for grants under this competition may be submitted electronically using the Grants.gov Apply site (Grants.gov), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: August 24, 2012.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/applicants/get_registered.jsp.*

7. *Other Submission Requirements:* Applications for grants under this competition may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications.*

We are participating as a partner in the Governmentwide *Grants.gov* Apply

site. The Personnel Preparation in Special Education, Early Intervention, and Related Services, CFDA number 84.325K, is included in this project. We request your participation in *Grants.gov.*

If you choose to submit your application electronically, you must use the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

You may access the electronic grant application for the Personnel Preparation in Special Education, Early Intervention, and Related Services, CFDA number 84.325K at *www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.325, not 84.325K).

Please note the following:

- Your participation in Grants.gov is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov,* we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov.*
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *http://www.G5.gov.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.
- If you submit your application electronically, you must upload all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- If you submit your application electronically, you must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues With the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov,* please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov,* along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

b. *Submission of Paper Applications by Mail.*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325K), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not

accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325K) 550 12th Street SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* (a) We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

(b) In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The Standing Panel requirements under IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that, for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities Program. These measures include: (1) The percentage of Special Education Personnel Development-projects that incorporate evidence-based practices into their curriculum; (2) the percentage of scholars completing Special Education Personnel Development-funded programs who are knowledgeable and skilled in evidence-based practices for infants, toddlers, children and youth with disabilities; (3) the percentage of Special Education Personnel Development-funded scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of Special Education Personnel Development-funded degree/certification recipients who are working in the area(s) for which they were prepared upon program completion; (5) the percentage of Special Education Personnel Development-funded degree/certification recipients who are working

in the area(s) for which they were prepared upon program completion and who are fully qualified under IDEA; (6) the percentage of Special Education Personnel Development degree/certification recipients who maintain employment in the area(s) for which they were prepared for three or more years and who are fully qualified under IDEA; and (7) the Federal cost per fully qualified degree/certification recipient.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: See chart in the *Award Information* section in this notice for the name, room number, telephone number, and email address of the contact person for each Focus Area of this competition. You can write to the Focus Area contact person at the following address: U.S. Department of Education, 400 Maryland Avenue SW., Potomac Center Plaza (PCP), Washington, DC 20202–2600.

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 8, 2012.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2012–11415 Filed 5–10–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Promise Neighborhoods Program—Planning Grant Competition, Correction

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice; correction.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.215P (Planning grants).

SUMMARY: On April 20, 2012, the Office of Innovation and Improvement in the U.S. Department of Education published in the **Federal Register** (77 FR 23690) a notice inviting applications for new awards for fiscal year (FY) 2012 for the Promise Neighborhoods planning grant competition (2012 Planning Grant NIA). This notice corrects an error in the deadline for transmittal of applications.

DATES: Deadline for Transmittal of Applications: July 27, 2012.

SUPPLEMENTARY INFORMATION:

Correction

In section IV, Application and Submission Information, the 2012 Planning Grant NIA indicates that the deadline for transmittal of applications is June 19, 2012, which is incorrect. We correct this NIA as follows:

On page 23700, third column, we correct the Deadline for Transmittal of Applications date to read ''July 27, 2012.''

Program Authority: 20 U.S.C. 7243–7243b.

VIII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW., room 4W256, Washington, DC 20202. Telephone: (202) 453–5638 or by email: *PromiseNeighborhoods@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 4, 2012.

James H. Shelton, III,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2012–11255 Filed 5–10–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records

AGENCY: Office of Chief Information Officer, Department of Education.

ACTION: Notice of deletion of existing system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of Education (Department) deletes one system of records from its existing inventory of systems of records subject to the Privacy Act.

DATES: This deletion is effective May 11, 2012.

FOR FURTHER INFORMATION CONTACT: Danny Harris, Director, Office of the Chief Information Officer, U.S. Department of Education, 555 New Jersey Avenue NW., room PCP–9112, Washington, DC 20208–0001. Telephone: (202) 245–6252.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities may obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed in this section.

SUPPLEMENTARY INFORMATION: The Department deletes one system of records from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The deletion is not within the purview of subsection (r) of the Privacy Act, which requires submission of a report on a new or altered system of records.

This system of records is no longer needed because this system has been decommissioned. Further, this system of records is no longer retrievable; therefore, the following system of records is deleted:

1. (18–04–03) ED Web Personalization Pilot Data Collection, 66 FR 46688–46690 (September 6, 2001).

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 3, 2012.

Danny Harris,

Director, Office of the Chief Information Officer.

For the reasons discussed in the preamble, the Director of the Office of the Chief Information Officer deletes the following system of records:

System No.	System name
18–04–03	ED Web Personalization Pilot Data Collection.

[FR Doc. 2012–11088 Filed 5–10–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13305–004]

Whitestone Power and Communications; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Terms and Conditions, and Fishway Prescriptions, and Waiving the Timing Requirement for Filing Competing Development Applications

Take notice that the following hydrokinetic pilot project license application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Pilot Project License.

b. Project No.: 13305–004.

c. Date filed: April 17, 2012.

d. *Applicant:* Whitestone Power and Communications.

e. *Name of Project:* Whitestone Poncelet River-In-Stream-Energy-Conversion Project (also known as the Microturbine Hydrokinetic River-In-Stream-Energy-Conversion Project)

f. *Location:* The proposed project would be located on the Tanana River near Delta Junction, Alaska. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791a–828c.

h. *Applicant Contact:* Steven M. Selvaggio, Whitestone Power and Communications, P.O. Box 1630, Delta Junction, Alaska 99737; phone: (907) 895–4938.

i. *FERC Contact:* Dianne Rodman, telephone (202) 502–6077, and email *dianne.rodman@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, recommendations, terms and conditions, and fishway prescriptions: 30 days from the issuance of this notice; reply comments are due 60 days from the issuance date of this notice.

Motions to intervene, protests, comments, recommendations, terms and conditions, and fishway prescriptions may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov or toll* free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. Project *Description:* The project would consist of: (1) A 12-foot-wide, 16-foot-diameter Poncelet undershot water wheel; (2) a 34-foot-long, 19- to 24-foot-wide aluminum-frame floatation platform mounted on a 34-foot-long, 3.5-foot-diameter high-density-polyethylene (HDPE) pontoon and a 34-foot-long, 3-foot-diameter HDPE pontoon; (3) a 100-kilowatt turbine/generator unit; (4) a 33-foot-long, 3.5-foot-wide gangway from the shore to the floating pontoon; (5) three anchoring cables to secure the floatation platform to the shore, comprising a 30-foot-long primary safety tether, a 117-foot-long primary cable, and a 100-foot-long secondary cable; (6) an approximately 900-foot-long transmission cable from the floatation platform to an existing Golden Valley Electric Association distribution line; and (7) appurtenant facilities. The project is anticipated to operate from April until October, with an estimated annual generation of 200 megawatt-hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at

http://www.ferc.gov using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST,'' ''MOTION TO INTERVENE,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''FISHWAY PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b) except to the extent that this notice establishes deadlines different from those in the regulation. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. Procedural Schedule:

The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of recommendations, terms and conditions, and fishway prescriptions	June 1, 2012.
Commission issues Single Environmental Assessment (EA)	July 31, 2012.
Comments on EA	August 30, 2012.

p. Waiver of deadline to file competing applications filed pursuant to a notice of intent:

Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application or a notice of intent to file such an application. Section 4.36(b)(2) of the Commission's regulations, which allows 120 days from the specified intervention deadline date for interested parties to file competing development applications in which timely notices of intent have been submitted, is hereby waived. Due to the expedited nature of the pilot project licensing procedures, the submission of a timely notice of intent will instead allow an interested person to file the competing development application no later than 30 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant named in this public notice.

Dated: May 2, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11361 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP12–440–000]

Kinder Morgan Texas Pipeline LLC; Notice of Application

Take notice that on April 30, 2012, Kinder Morgan Texas Pipeline LLC (KMTP), 500 Dallas Street, Suite 1000, Houston, Texas 77002, filed in the above referenced docket an application pursuant to section 3 of the Natural Gas Act (NGA) and Part 153.16(b) of the Commission's regulations, requesting authorization to amend its existing NGA section 3 authorization and Presidential Permit to increase the authorized design capacity of its border facilities at the United States-Mexico International Boundary line near Salineno, in Starr County, Texas from approximately 375 MMcf per day to 425 MMcf per day. The proposed amendment would allow KMTP to continue to provide Pemex-Gas Y Petroquimica Basica (Pemex) with increased gas supplies as Pemex finishes repairing a damaged pipeline in Mexico that has diminished its access to other natural gas supply sources and resulted in curtailments. KMTP proposes no construction or modification to its previously approved facilities. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Lee Baskin, Director, Regulatory, Kinder Morgan Texas Intrastate Pipeline Group, 500 Dallas Street, Suite 1000, Houston, TX 77002, by telephone at (713) 369–8810, by facsimile at (713) 495–4845, or by email at *lee_baskin@kindermorgan.com* or Melinda K. Winn, Assistant General Counsel, Kinder Morgan Energy Partners, L.P., One Allen Center, 500 Dallas Street, Suite 1000, Houston, TX 77002, by telephone at (713) 369–8780, by facsimile at (303) 984–3737, or by email at *Melinda_Winn@kindermorgan.com*.

Pursuant to Section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the

Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Motions to intervene, protests and comments may be filed electronically via the Internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: May 9, 2012.

Dated: May 2, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11357 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11402–073]

City of Crystal Falls, MI; Notice of Application for Temporary Variance of License and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Temporary variance of license.

b. *Project No.:* 11402–073.

c. *Date Filed:* May 30, 2012.

d. *Applicant:* City of Crystal Falls, MI.

e. *Name of Project:* Crystal Falls Project.

f. *Location:* The project is located on the Paint River in the City of Crystal Falls, Michigan.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Dave Graff, City of Crystal Falls, 401 Superior Avenue, Crystal Falls, MI 49920, (906) 875–6650.

i. *FERC Contact:* Rebecca Martin, (202) 502–6012, *Rebecca.martin@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* June 4, 2012.

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. Please include the project number (P–11402–073) on any comments or motions filed.

k. *Description of Application:* The City of Crystal Falls requests a variance for the following: (1) Impoundment drawdown will begin on July 27, 2012, at a rate of 1.0 foot per day for the first four days from its summer elevation of 1333.98 feet. Once the impoundment is drawn down 4.0 feet, then the drawdown rate will switch to 1.5 feet per day until a 20 foot drawdown is reached. (2) Once drawdown is complete the city will revert back to run-of-river where the outflow will match the inflow. (3) The impoundment will be filled as the inflow allows, while maintaining 150 cubic feet per second outflow. This shall occur as soon as possible but no later than November 1, 2012. (4) The scheduled water quality study will be conducted in July and August of 2013 rather than in 2012. (5) The barrier net will be lifted when the generators are no longer generating while the impoundment is in the drawdown state. During the drawdown the City will conduct surveys for stranded mussels and fish. Additionally, recreational access will be limited to canoes, kayaks, and small boats during the drawdown.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field (P–2698) to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be

notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the amendment application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11351 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 739–028]

Appalachian Power Company; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-project use of project lands and waters.

b. *Project No:* 739–028.

c. *Date Filed:* April 2, 2012.

d. *Applicant:* Appalachian Power Company.

e. *Name of Project:* Claytor Hydroelectric Project.

f. *Location:* Claytor Lake in Pulaski County, Virginia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Teresa Rogers, American Electric Power, Hydro Generation, P.O. Box 2021, Roanoke, VA 24022–2121, (540) 985–2441..

i. *FERC Contact:* Mark Carter, (678) 245–3083, *mark.carter@ferc.gov*.

j. *Deadline for Filing Comments, Motions To Intervene, and Protests:* June 4, 2012.

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–739–028) on any comments, motions, or recommendations filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Application:* Appalachian Power Company (licensee) requests Commission approval to permit Larry and Barbara Patton (permittee) to construct a single-slip boat dock on Claytor Lake. The 636-square-foot dock would replace an existing dock that had been dislodged from the shoreline. The application also includes a request for a variance from the project's approved shoreline management plan to allow the proposed use, because it is located near a stream bed in the back of a cove with a steep slope and is classified as conservation/environmental. No vegetation removal or dredging is proposed.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions To Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the

appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: May 3, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11349 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC12–97–000.
Applicants: Avenal Park LLC, Sand Drag LLC, Sun City Project LLC, NRG Solar Blythe LLC.
Description: Application of Avenal Park LLC, et al. for Authorization of Disposition of Jurisdictional Facilities and Requests for Confidential Treatment and Expedited Consideration.
Filed Date: 5/3/12.
Accession Number: 20120503–5123.
Comments Due: 5 p.m. ET 5/24/12.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG12–65–000.
Applicants: Bethel Wind Energy LLC.
Description: Notice of Self-Certification as an Exempt Wholesale Generator of Bethel Wind Energy LLC.
Filed Date: 5/3/12.
Accession Number: 20120503–5098.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: EG12–66–000.
Applicants: Rippey Wind Energy LLC.
Description: Notice of Self-Certification as an Exempt Wholesale Generator of Rippey Wind Energy LLC.
Filed Date: 5/3/12.
Accession Number: 20120503–5100.
Comments Due: 5 p.m. ET 5/24/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2875–006.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance Filing per 4/4/2012 Order in ER11–2875 to be effective 12/19/2011 to be effective 12/19/2011.
Filed Date: 5/4/12.
Accession Number: 20120504–5119.
Comments Due: 5 p.m. ET 5/25/12.

Docket Numbers: ER11–2875–007.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance Filing per 4/4/2012 Order in ER11–2875 to be effective 1/31/2012 to be effective 1/31/2012.
Filed Date: 5/4/12.
Accession Number: 20120504–5125.
Comments Due: 5 p.m. ET 5/25/12.

Docket Numbers: ER11–2875–008.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance Filing per 4/4/2012 Order in ER11–2875 to be effective 6/30/2012 to be effective 6/30/2012.
Filed Date: 5/4/12.
Accession Number: 20120504–5137.
Comments Due: 5 p.m. ET 5/25/12.

Docket Numbers: ER12–1571–001.
Applicants: Verso Bucksport LLC.
Description: Amendment to MBR Application to be effective 6/18/2012.
Filed Date: 5/4/12.
Accession Number: 20120504–5114.
Comments Due: 5 p.m. ET 5/25/12.

Docket Numbers: ER12–1633–001.
Applicants: U.S. Energy Partners, LLC.
Description: U.S. Energy Amendment to Baseline MBR Filing to be effective 7/1/2012.
Filed Date: 5/4/12.
Accession Number: 20120504–5134.
Comments Due: 5 p.m. ET 5/25/12.

Docket Numbers: ER12–1715–000.
Applicants: Midwest Independent Transmission System.
Description: G578 LGIA Termination to be effective 7/4/2012.
Filed Date: 5/4/12.
Accession Number: 20120504–5053.
Comments Due: 5 p.m. ET 5/25/12.

Docket Numbers: ER12–1716–000.
Applicants: Your Energy Holdings, LLC.
Description: Market-Based Rates Application to be effective 6/27/2012.
Filed Date: 5/4/12.
Accession Number: 20120504–5084.
Comments Due: 5 p.m. ET 5/25/12.

Docket Numbers: ER12–1717–000.
Applicants: PJM Interconnection, L.L.C.
Description: Queue Position U2–077 & W1–001; Original Service Agreement No. 3313 to be effective 4/4/2012.
Filed Date: 5/4/12.
Accession Number: 20120504–5142.
Comments Due: 5 p.m. ET 5/25/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 4, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–11371 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC12–96–000.
Applicants: Sierra Pacific Power Company.
Description: Application of Sierra Pacific Power Company for Order Authorizing Acquisition of Jurisdictional Facilities under FPA Section 203 and Request for Expedited Action.
Filed Date: 5/2/12.
Accession Number: 20120502–5203.

Comments Due: 5 p.m. ET 5/23/12.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG12–64–000.
Applicants: High Plains Ranch II, LLC.
Description: High Plains Ranch II, LLC—Notice of Self Certification of Exempt Wholesale Generator Status.
Filed Date: 5/3/12.
Accession Number: 20120503–5057.
Comments Due: 5 p.m. ET 5/24/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4105–001.
Applicants: Southwest Power Pool, Inc.
Description: Order No. 745 Compliance to be effective 12/31/9998.
Filed Date: 5/2/12.
Accession Number: 20120502–5189.
Comments Due: 5 p.m. ET 5/23/12.

Docket Numbers: ER12–1151–000.
Applicants: Pacific Gas and Electric Company.
Description: Compliance Refund Report for Marsh Landing E&P Agreement to be effective N/A.
Filed Date: 5/3/12.
Accession Number: 20120503–5003.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1471–001.
Applicants: Canastota Windpower, LLC.
Description: Canastota Windpower, LLC submits tariff filing per 35.17(b): Canastota Windpower, LLC Amendment to Electric Tariff to be effective 5/4/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5097.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1613–001.
Applicants: Hill Energy Resource & Services, LLC.
Description: Amendments to Hill Energy Resource & Services, LLC Electric Tariff to be effective 5/1/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5007.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1706–000.
Applicants: NV Energy, Inc.
Description: Service Agreement No. 12–00030 Mt Wheeler Power NITS Agreement to be effective 6/1/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5000.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1707–000.
Applicants: Liberty Power Wholesale Supply, LLC.
Description: Market-Based Rate Application to be effective 5/3/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5006.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1708–000.
Applicants: Midwest Independent Transmission System Operator, Inc., ITC Midwest LLC.
Description: ITCM–Northern Iowa Windpower IA to be effective 7/3/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5034.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1709–000.
Applicants: New York Independent System Operator, Inc., Niagara Mohawk Power Corporation.
Description: Agreement No. 1488, Niagara Mohawk and Selkirk Cogen Partners IA to be effective 4/1/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5042.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1710–000.
Applicants: Southwest Power Pool, Inc.
Description: Submission of Notice of Cancellation—Service Agreements 2021R1 and 2022R1 to be effective 4/1/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5050.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1711–000.
Applicants: High Plains Ranch II, LLC.
Description: High Plains Ranch II, LLC submits tariff filing per 35.12: Application for Market-Based Rate Authority to be effective 6/25/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5056.
Comments Due: 5 p.m. ET 5/24/12.

Docket Numbers: ER12–1712–000.
Applicants: ITC Midwest LLC.
Description: ITC Midwest LLC submits tariff filing per 35.13(a)(2)(iii: Filing of Agreements with MidAmerican Energy Company to be effective 7/3/2012.
Filed Date: 5/3/12.
Accession Number: 20120503–5084.
Comments Due: 5 p.m. ET 5/24/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 03, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–11372 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL12–63–000]

Independent Market for PJM v. Unnamed Participant; Notice of Complaint

Take notice that on May 1, 2012, pursuant to section 206 of the Rules of Practice and Procedure of the Federal Energy Regulatory Commission (Commission), 18 CFR 385.206, Independent Market for PJM (Complainant) filed a formal complaint against an unnamed participant (Respondent) requesting that the Commission direct Respondent to submit a Sell Offer in the Base Residual Auction that opens May 7, 2012, for the 2015/2016 Delivery Year calculated on a basis consistent with a competitive market as required by PJM's Minimum Offer Price Rule.

Complainants certify that copies of the complaint were served on the contacts for Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission,

888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on May 21, 2012.

Dated: May 2, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11359 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EG12–31–000; EG12–32–000; et al.]

Quantum Choctaw Power, LLC, USG Nevada LLC, et al.; Notice of Effectiveness of Exempt Wholesale Generator Status

	Docket Nos.
Quantum Choctaw Power, LLC.	EG12–31–000
USG Nevada LLC	EG12–32–000
Kawailoa Wind, LLC	EG12–33–000
Mariposa Energy, LLC	EG12–34–000
Stephentown Spindle, LLC	EG12–35–000

Take notice that during the month of April 2012, the status of the above-captioned entities as Exempt Wholesale Generators became effective by operation of the Commission's regulations. 18 CFR 366.7(a).

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11358 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP12–124–000; CP11–40–000; CP10–34–000]

East Cheyenne Gas Storage, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed West Peetz Well Plan Amendment and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the West Peetz Well Plan Amendment involving construction and operation of facilities by East Cheyenne Gas Storage, LLC (East Cheyenne) in Logan County, Colorado. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project amendment. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Please note that the scoping period will close on June 2, 2012.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Summary of the Proposed Project

The proposed project would amend the East Cheyenne Gas Storage Project, which consists of construction and operation of a natural gas storage facility in two nearly depleted oil production fields in Logan County, Colorado. The project was originally authorized by the Commission on August 2, 2010 under Docket No. CP10–34–000, and amended on April 12, 2011 under Docket No. CP11–40–000. On January 31, 2012, under Docket No. CP12–35–000, the Commission further amended the certificate by revising the maximum reservoir pressure for the D Sands zone in the West Peetz Field. East Cheyenne is not seeking to revise the maximum reservoir pressure and therefore does not seek to amend the certificate issued to East Cheyenne in Docket No. CP12–35–000.

Following issuance of the August 2 and April 12 Orders, East Cheyenne further evaluated the West Peetz D Sands Formation. Based on the findings, East Cheyenne determined that they should modify the proposed number and location of wells, in addition to well design and installation methods, to develop the authorized working gas capacity for optimal performance. The proposed amendment would involve reconfiguration of the injection/withdrawal (I/W) wells and associated piping, addition of a produced water disposal well and associated piping, and two monitoring wells, and an increase in the amount of cushion gas capacity. Additionally, East Cheyenne would no longer use ten of the originally proposed access roads. The proposed amendment consists of the following changes to the East Cheyenne Gas Storage Project:

- Relocate and convert four currently certificated wells from horizontal to vertical I/W wells;
- Construct four additional I/W wells, three of which would be vertical and the fourth a slant well;
- Plug and abandon two previously certificated and operating I/W wells and replace them with two new vertical I/W wells;
- Install two additional observation wells and one additional produced water disposal well;
- Reconfigure related natural gas lateral pipelines; and
- Install and reconfigure related produced water mainline, laterals, and disposal pipelines.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

The certificated East Cheyenne Gas Storage Project is currently storing

[1] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

natural gas in nearly depleted reservoirs that underlie an area of approximately 2,360 acres, with an additional 3,400 acres serving as a storage buffer area. The revised facilities would be located in previously surveyed areas within the project site. Construction of the revised facilities would require approximately 501.9 acres of land, an increase of 26 acres from the previous project total of 485.8 acres. Following construction, East Cheyenne would maintain about 200.2 acres as permanent facilities and right-of-way; a decrease of 1.3 acres from the previous project total of 201.5 acres. The remaining 301.7 acres of land would be restored and allowed to revert to its former use.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider comments filed during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project amendment under these general headings:

- Geology and soils;
- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife;
- Air quality and noise;
- Endangered and threatened species; and
- Public safety.

We will also evaluate reasonable alternatives to the proposed project or portions of the project amendment, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section below.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project amendment. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that they will be received in Washington, DC on or before June 2, 2012.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP12–124–000) with your submission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*.

(1) You can file your comments electronically using the eComment feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing'';

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary

[2] ''We'', ''us'', and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (i.e., CP12–124). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: May 3, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11350 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP12–164–000]

Texas Eastern Transmission, LP; Notice of Intent To Prepare an Environmental Assessment for the Proposed Line 11–AUX–1 Abandonment Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an Environmental Assessment (EA) that will discuss the environmental impacts of the Line 11–Aux–1 Abandonment Project involving abandonment of facilities by Texas Eastern Transmission, LP (Texas Eastern) in Montgomery County, Texas. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Please note that the scoping period will close on June 4, 2012.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

Texas Eastern provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?''. This fact sheet addresses a number of typically-asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Summary of the Proposed Project

Texas Eastern proposes to abandon in place approximately 5.7 miles of its 24-inch-diameter Line 11 pipeline currently located under Lake Conroe in Montgomery County, Texas. Texas Eastern originally constructed Line 11 in 1952 and the 5.7-mile-long segment is between Milepost 97.54 and 103.21. Texas Eastern re-designated this segment as Line 11–Auxndash;1 in 1971 when it installed a new parallel segment of pipeline to serve as the primary crossing of Lake Conroe. Texas Eastern has not provided service for several years on Line 11–Auxndash;1 and it is not necessary to meet Texas Eastern's firm service obligations. Texas Eastern would fill Line 11–Auxndash;1 with water and cap it below ground. Texas Eastern would also remove related ancillary pipe casing vents and piping components, and disconnect a related rectifier.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

Abandonment of the proposed facilities would disturb approximately 0.5 acre of land, including 10,500 square feet at the southern end of the 5.7-mile-long segment and 11,250 square feet at the northern end. All construction areas would be within Texas Eastern's existing, maintained right-of-way. Following abandonment activities, Texas Eastern would retain rights to the permanent easement associated with the Line 11–Aux–1 pipeline.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us[2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- Land use;
- Water resources, fisheries, and wetlands;
- Cultural resources;
- Vegetation and wildlife;
- Air quality and noise;
- Endangered and threatened species; and
- Public safety.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 4.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the

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[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before June 4, 2012.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP12–164–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You can file your comments electronically using the eComment feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are current right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (i.e., CP12–164). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11356 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–6870–000]

Jamar, John P.; Notice of Filing

Take notice that on May 3, 2012, John P. Jamar submitted for filing, an application for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b) (2008) and section

45.8 of Title 18 of the Code of Federal Regulations, 18 CFR 45.8.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on May 24, 2012.

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11360 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–1692–000]

Galaxy Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Galaxy Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is May 24, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 4, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–11384 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14390–000]

Milford Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On April 19, 2012, Milford Hydro, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Milford Dam Hydroelectric Project, which would be located on the Republican River, in Geary County, Kansas. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of: (1) A powerhouse; (2) installation of two 1.85-megawatt propeller type turbines; (3) a proposed 4,440-foot-long, 12.7-kilovolt transmission line; (4) a 30-foot-long bifurcation structure equipped with three slide gates; (5) a 160-foot-long penstock; and (6) appurtenant facilities. The proposed Milford Dam Hydroelectric Project would have an estimated average annual generation of 20.917 gigawatt-hours.

Applicant Contact: Mark Boumansour, Milford Hydro, LLC, 1035 Pearl Street, 4th Floor, Boulder, CO 80302; phone: (720) 295–3317.

FERC Contact: Bryan Roden-Reynolds at (202) 502–6618, or via email at *bryan.roden-reynolds@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*). Commenter can submit brief comment up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end

of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14218) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11355 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14359–000]

Greybull Valley Irrigation District; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On February 1, 2012, Greybull Valley Irrigation District filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Greybull Valley Dam Hydroelectric Power Project (Greybull Valley Dam Project or project) to be located on Roach Gulch, near Meeteetse, Park County, Wyoming. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would utilize the existing Roach Gulch dam and reservoir having a total storage capacity of 33,169 acre-feet at a normal high water level elevation of 4,953 feet mean sea level and an existing 1,150-foot-long, 60-inch-diameter steel penstock, and would consist of the following new features: (1) A powerhouse containing two turbine/generator units rated at 2.5 megawatts each at 140 feet of net head; (2) a 3-mile-long, 69-kilovolt transmission line extending from the project to a transmission line owned by Big Horn Rural Electric Company (the point of interconnection); and (3) appurtenant facilities. The estimated annual generation of the Greybull Valley Dam Project would be 10 gigawatt-hours.

Applicant Contacts: Mr. Lee Allen, 989 Highway 20 West, P.O. Box 44, Emblem, Wyoming 82422; phone: (307) 762–3555. Mr. William Schlenker, 989 Highway 20 West, P.O. Box 44, Emblem, Wyoming 82422; phone: (307) 762–3555.

FERC Contact: Kim Nguyen; phone: (202) 502–6105.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14359) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11354 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12604–002]

Greybull Valley Irrigation District; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On February 1, 2012, the Greybull Valley Irrigation District filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Lower Sunshine Reservoir Hydroelectric Power Project (Lower Sunshine Project or project) to be located on Sunshine Creek, near Meeteetse, Park County, Wyoming. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would utilize the existing Lower Sunshine dam and reservoir having a total storage capacity of 56,378 acre-feet at elevation 6,277 feet mean sea level, and would consist of the following new features: (1) A 50-foot-long, 6-foot-diameter penstock extending from the existing conduit to the powerhouse; (2) a powerhouse containing two turbine/generator units totaling 5 megawatts or less in capacity at 170 feet of net head; (3) a tailrace discharging flows to Sunshine Creek; (4) a 1,700-foot-long, 25-kilovolt (kV) transmission line extending from the project to a 69-kV transmission line owned by the Western Area Power Administration and Rocky Mountain Power (the point of interconnection); and (5) appurtenant facilities. The estimated annual generation of the Lower Sunshine Project would be 12.4 gigawatt-hours.

Applicant Contacts: Mr. Lee Allen, 989 Highway 20 West, P.O. Box 44, Emblem, Wyoming 82422; phone: (307) 762–3555. Mr. William Schlenker, 989 Highway 20 West, P.O. Box 44, Emblem, Wyoming 82422; phone: (307) 762–3555.

FERC Contact: Kim Nguyen; phone: (202) 502–6105.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of

intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–12604–002) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11353 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12595–002]

Greybull Valley Irrigation District; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On February 1, 2012, the Greybull Valley Irrigation District filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Upper Sunshine Reservoir Hydroelectric Power Project (Upper Sunshine Project or project) to be located on Sunshine Creek, near Meeteetse, Park County, Wyoming. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would utilize the existing Upper Sunshine dam and reservoir having a total storage capacity of 53,515 acre-feet at elevation 6,595 feet mean sea level, and would consist of the following new features: (1) A 6-foot-diameter penstock extending from the existing conduit to the powerhouse adjacent to the dam; (2) a powerhouse containing one Francis turbine/generator unit rated at 5 megawatts or less at 150 feet of net head; (3) a tailrace channel discharging from the powerhouse to Sunshine Creek; (4) a 3-mile-long, 25-kilovolt transmission line extending from the project to a transmission line owned by Rocky Mountain Power (the point of interconnection); and (5) appurtenant facilities. The estimated annual generation of the Upper Sunshine Project would be 6 gigawatt-hours.

Applicant Contacts: Mr. Lee Allen, 989 Highway 20 West, P.O. Box 44, Emblem, Wyoming 82422; phone: (307) 762–3555. Mr. William Schlenker, 989 Highway 20 West, P.O. Box 44, Emblem, Wyoming 82422; phone: (307) 762–3555.

FERC Contact: Kim Nguyen; phone: (202) 502–6105.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–12595–002) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 4, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11352 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 308–005]

PacifiCorp Energy; Notice of Proposed Restricted Service List for a Programmatic Agreement for Managing Properties Included in or Eligible for Inclusion in the National Register of Historic Places

Rule 2010 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure provides that, to eliminate unnecessary expense or improve administrative efficiency, the Secretary may establish a restricted service list for a particular phase or issue in a proceeding.[1] The restricted service list should contain the names of persons on the service list who, in the judgment of the decisional authority establishing the list, are active participants with respect to the phase or issue in the proceeding for which the list is established.

Commission staff is consulting with the Oregon State Historic Preservation Officer (hereinafter, Oregon SHPO), and the Advisory Council on Historic Preservation (hereinafter, Council) pursuant to the Council's regulations, 36 CFR part 800, implementing section 106 of the National Historic Preservation Act, *as amended,* (16 U.S.C. section 470 f), to prepare and execute a programmatic agreement for managing properties included in, or eligible for inclusion in, the National Register of Historic Places at the Wallowa Falls Hydroelectric Project No. 308.

The programmatic agreement, when executed by the Commission and the Oregon SHPO would satisfy the Commission's section 106

[1] 18 CFR section 385.2010.

responsibilities for all individual undertakings carried out in accordance with the license until the license expires or is terminated (36 CFR 800.13[e]). The Commission's responsibilities pursuant to section 106 for the Wallowa Falls Hydroelectric Project would be fulfilled through the programmatic agreement, which the Commission proposes to draft in consultation with certain parties listed below. The executed programmatic agreement would be incorporated into any Order issuing a license.

PacifiCorp Energy, as licensee for the Wallowa Falls Project No. 308, and the Nez Perce Tribe, Confederated Tribes of Umatilla Indian Reservation, Confederate Tribes of the Colville Reservation, and Wallowa-Whitman National Forest have expressed an interest in this preceding and are invited to participate in consultations to develop the programmatic agreement.

For purposes of commenting on the programmatic agreement, we propose to restrict the service list for the aforementioned project as follows:

John Eddins or Representative, Office of Planning and Review, Advisory Council on Historic Preservation, 1100 Pennsylvania Ave., NW., Suite 809, Washington, DC 20004.

Anthony King or Representative, Wallowa-Whitman National Forest, 201 E. 2nd Street, Joseph, OR 97846.

Catherine Dickson or Representative, Cultural Resources Protection Program, Confederated Tribes of the Umatilla Indian Reservation, 46411 Timine Way, Pendleton, Oregon 97801.

Arrow Coyote or Representative, Confederate Tribes of the Colville Reserv., P.O. Box 150, Nespelem, WA 99155.

Keith Patrick Baird, THPO, Cultural Resources Program, Nez Perce Tribe, P.O. Box 365, Lapwai, ID 83540–0365.

Russ Howison or Representative, PacifiCorp Energy, 825 NE Multnomah, Suite 1500, Portland, OR 97232.

John Pouley or Representative Oregon Parks and Recreation Department Summer St., NE., Suite C Salem, OR 97301.

Any person on the official service list for the above-captioned proceeding may request inclusion on the restricted service list, or may request that a restricted service list not be established, by filing a motion to that effect within 15 days of this notice date. In a request for inclusion, please identify the reason(s) why there is an interest to be included. Also please identify any concerns about historic properties, including Traditional Cultural Properties. If historic properties are to be identified within the motion, please use a separate page, and label it NON–PUBLIC Information.

Any such motions may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the ''eFiling'' link. For a simpler method of submitting text only comments, click on ''Quick Comment.'' For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please put the project number (P–308–005) on the first page of the filing.

If no such motions are filed, the restricted service list will be effective at the end of the 15 day period. Otherwise, a further notice will be issued ruling on any motion or motions filed within the 15 day period.

Dated: May 3, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–11362 Filed 5–10–12; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9670–5]

Clean Water Act Section 303(d): Availability of List Decisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice and Request for Comments.

SUMMARY: This notice announces EPA's decision identifying certain water quality limited waterbodies, and the associated pollutant, in Utah to be listed pursuant to the Clean Water Act Section 303(d)(2), and requests public comment. Section 303(d)(2) requires that States submit, and EPA approve or disapprove, lists of waters for which existing technology-based pollution controls are not stringent enough to attain or maintain State water quality standards and for which total maximum daily loads (TMDLs) must be prepared.

On April 11, 2012, EPA disapproved Utah's decision to not include Kanab Creek and tributaries, from the state line to irrigation diversion at confluence with Reservoir Canyon (''Kanab Creek and tributaries''), on the State's 2008 and 2010 Section 303(d) lists. EPA evaluated existing and readily available data and information and concluded that the applicable water quality criterion for total dissolved solids (TDS) for these waters is being exceeded. Based on this evaluation, EPA has determined that Kanab Creek and tributaries are not fully attaining the water quality standards established by the State of Utah and should be included on the State's lists of impaired waters.

EPA is providing the public the opportunity to review its decision to add these waters to Utah's 2008 and 2010 Section 303(d) lists, as required by 40 CFR 130.7(d)(2). EPA will consider public comments before transmitting its final listing decision to the State.

DATES: Comments must be submitted to EPA on or before June 11, 2012.

ADDRESSES: Comments on the proposed decision should be sent to Kris Jensen, Water Quality Unit (8EPR–EP), U.S. Environmental Protection Agency Region 8, 1595 Wynkoop Street, Denver, CO 80202–1129, telephone (303) 312–6237, facsimile (303) 312–7517, email *jensen.kris@epa.gov.* Oral comments will not be considered. Copies of EPA's letter concerning Utah's list that explains the rationale for EPA's decision can be obtained at EPA Region 8's Web site at *http://www.epa.gov/region08/water/tmdl,* or by writing or calling Ms. Jensen at the above address. Underlying documents from the administrative record for these decisions are available for public inspection at the above address. Please contact Ms. Jensen to schedule an inspection.

FOR FURTHER INFORMATION CONTACT: Kris Jensen at (303) 312–6237 or *jensen.kris@epa.gov.*

SUPPLEMENTARY INFORMATION: Section 303(d) of the Clean Water Act (CWA) requires that each state identify those waters for which existing technology-based pollution controls are not stringent enough to attain or maintain state water quality standards. For those

waters, states are required to establish TMDLs according to a priority ranking.

EPA's Water Quality Planning and Management regulations include requirements related to the implementation of Section 303(d) of the CWA (40 CFR 130.7). The regulations require states to identify water-quality-limited waters still requiring TMDLs every two years. The lists of waters still needing TMDLs must also include priority rankings, identify the pollutants causing the impairment, and must identify the waters targeted for TMDL development during the next two years (40 CFR 130.7).

Consistent with EPA's regulations, Utah submitted to EPA its listing decisions under Section 303(d)(2) in correspondence dated March 31, 2011 and April 21, 2011. On February 10, 2012, EPA partially approved with further review pending for Kanab Creek and tributaries, Utah's 2008 and 2010 listings of waters and associated priority rankings. On April 11, 2012, EPA disapproved Utah's decision to not include Kanab Creek and tributaries, from state line to irrigation diversion at confluence with Reservoir Canyon on the 2008 and 2010 lists. EPA solicits public comment on the addition of these waters to the State's list, as required by 40 CFR 130.7(d)(2).

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

Dated: April 26, 2012.

Martin Hestmark,

Acting Assistant Regional Administrator, Office of Ecosystems Protection and Remediation.

[FR Doc. 2012–11428 Filed 5–10–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9002–9]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/*.

Weekly receipt of Environmental Impact Statements

Filed 04/30/2012 Through 05/04/2012

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html*.

Supplementary Information: EPA is seeking agencies to participate in its e-NEPA electronic EIS submission pilot. Participating agencies can fulfill all requirements for EIS filing, eliminating the need to submit paper copies to EPA Headquarters, by filing documents online and providing feedback on the process. To participate in the pilot, register at: *https://cdx.epa.gov.*

EIS No. 20120136, Final Supplement, APHIS, NY, Bird Hazard Reduction Program, John F. Kennedy International Airport, Updated Information on the Efficacy and Impacts of the Gull Hazard Reduction Program and All Other Bird Hazard Management Activities, Queens County, NY, Review Period Ends: 06/13/2012, Contact: Martin S. Lowney 518–477–4837.

EIS No. 20120137, Draft EIS, USFS, 00, Mountain Pine Beetle Response Project, Implementing Multiple Resource Management Activities, Black Hills National Forest, Custer, Fall River, Lawrence, Meade, and Pennington Counties, SD and Crook and Weston Counties, WY, Comment Period Ends: 06/25/2012, Contact: Katie Van Alstyne 605–343–1567.

EIS No. 20120138, Draft EIS, USACE, FL, Tarmac King Road Limestone Mine, Construction, Issuance of Permit, Levy County, FL, Comment Period Ends: 07/11/2012, Contact: Edward Sarfert 850–439–9533.

EIS No. 20120139, Draft EIS, NPS, GA, Fort Pulaski National Monument General Management Plan and Wilderness Study, Implementation, Chatham County, GA, Comment Period Ends: 07/09/2012, Contact: David Libman 404–507–5701.

EIS No. 20120140, Final EIS, USAF, OH, Wright-Patterson Air Force Base (WPAFB) Project, Reconfigure and Relocate Facilities and Base Perimeter Fence Relocation in Area A, Fairborn, OH, Review Period Ends: 06/11/2012, Contact: Estella Holmes 937–522–3522.

EIS No. 20120141, Final EIS, USFS, CO, Beaver Creek Mountain Improvements Project, Special Use Permit, White River National Forest, Eagle County, CO, Review Period Ends: 06/11/2012, Contact: Don Dressler 970–827–5157.

EIS No. 20120142, Draft EIS, USN, 00, Atlantic Fleet Training and Testing Activities, To Support and Conduct Current, Emerging, and Future Training and Testing Activities along the Eastern Coast of the U.S. and Gulf of Mexico, Comment Period Ends: 06/25/2012, Contact: Jene Nissen 757–836–5221.

EIS No. 20120143, Draft EIS, USN, 00, Hawaii-Southern California Training and Testing Activities, To Support and Conduct Current, Emerging, and Future Training and Testing Activities off Southern California and around the Hawaiian Islands, CA, HI, Comment Period Ends: 06/25/2012, Contact: Alex Stone 619–545–8128.

EIS No. 20120144, Draft EIS, USAF, CA, F–15 Aircraft Conversion, 144th Fighter Wing, California National Guard, To Convert the Unit from the F–16 Fighting Falcon Aircraft and Operations to the F–15 Eagle Aircraft and Operations at Fresno-Yosemite International Airport, Fresno County, CA, Comment Period Ends: 06/25/2012, Contact: Robert Dogan 240–612–8859.

EIS No. 20120145, Draft EIS, BR, CA, Water Transfer Program for the San Joaquin River Exchange Contractors Water Authority, 2014–2038, To Execute Agreements for Water Transfers/or Exchanges, San Joaquin Valley, Fresno, Madera, Merced, and Stanislaus Counties, CA, Comment Period Ends: 07/03/2012, Contact: Bradley Hubbard 916–978–5204.

Dated: May 8, 2012.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2012–11467 Filed 5–10–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to

minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before July 10, 2012. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Judith B. Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov*. To submit your PRA comments by email send them to: *PRA@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0168.

Title: Section 43.43, Report of Proposed Changes in Depreciation Rates.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 24 respondents; 24 responses.

Estimated Time per Response: 250 hours.

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 152, 154, 161, 201–205 and 218–220 of the Communications Act of 1934, as amended.

Total Annual Burden: 6,000 hours.

Total Annual Cost: $851,160.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: The Commission is seeking OMB approval for an extension (no change in the reporting and/or recordkeeping requirements). This is being submitted to the OMB to obtain the full three year approval from them and keep this collection from lapsing. The Commission is reporting an increase in annual costs which is due to an increase in the Commission's filing fee (per 47 CFR section 1.1105).

Section 43.43 of the Commission's rules establishes the reporting requirements for depreciation prescription purposes. Communications common carriers with annual reporting revenues of $138 million or more that the Commission has found to be dominant must file information specified in section 43.43 before making any change in the deprecation rates applicable to their operating plant.

Section 220 of the Communications Act of 1934, as amended, also allows the Commission, in its discretion, to prescribe the form of any and all accounts, records, and memoranda to be kept by carriers subject to the Act, including the accounts, records, and memoranda of the movement of traffic, as well as receipts and expenditures of moneys. Carriers are required to file four summary exhibits along with the underlying data used to generate them, and must provide the depreciation factors (i.e., life, salvage, curve shape, depreciation reserve) required to verify the calculation of the carrier's depreciation expenses and rates. Mid-sized carriers are no longer required to file theoretical reserve studies. Certain price cap incumbent LECs in certain instances may request a waiver of the depreciation prescription process.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2012–11366 Filed 5–10–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collections Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: The Federal Communications Commission (FCC), as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act (PRA) of 1995. Comments are requested concerning whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before June 11, 2012. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to the Federal Communications Commission via email to *PRA@fcc.gov* and *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0214.

Title: Sections 73.3526 and 73.3527, Local Public Inspection Files; Sections 76.1701 and 73.1943, Political Files.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Parties: Business or other for-profit entities; Not for-profit institutions; Individuals or households.

Number of Respondents and Responses: 24,558 respondents; 59,056 responses.

Estimated Time per Response: 1 hour to 104 hours.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 152, 154(i), 303, 307 and 308.

Total Annual Burden: 2,158,080 hours.

Total Annual Costs: $882,236.00.

Privacy Act Impact Assessment: The FCC is preparing a PIA.

Nature and Extent of Confidentiality: The FCC is preparing a system of records, FCC/MB–2, ''Broadcast Station Public Inspection Files,'' to cover the personally identifiable information (PII) that may be included in the broadcast station public inspection files. Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission is seeking final approval of the information collection requirements that were adopted in FCC 12–44 and contained in collection 3060–0214 from the Office of Management and Budget (OMB). On April 27, 2012, the Commission released a Second Report and Order, MB Docket Nos. 00–168 and 00–44; FCC 12–44. This Order adopted information collection requirements that support the Commission's public file rules that are codified at 47 CFR 73.3526 and 73.3527. 47 CFR 73.3526 and 73.3527 require that licensees and permittees of commercial and noncommercial AM, FM and TV stations maintain a file for public inspection at its main studio or at another accessible location in its community of license. The contents of the file vary according to type of service and status. The contents include, but are not limited to, copies of certain applications tendered for filing, a statement concerning petitions to deny filed against such applications, copies of ownership reports, statements certifying compliance with filing announcements in connection with renewal applications, a list of donors supporting specific programs, and a list of community issues addressed by the station's programming.

These rules also specify the length of time, which varies by document type, that each record must be retained in the public file. The public and FCC use the data to evaluate information about the licensee's performance and to ensure that station is addressing issues concerning the community to which it is licensed to serve.

The information collection requirements consist of:

Pursuant to 47 CFR 73.1943(d), television station licensees or applicants must place the contents of its political file on the Commission's Web site on a going-forward basis. Pursuant to 47 CFR 73.3526(b), commercial television station licensees or applicants must place the contents of their public inspection file as required by 47 CFR 73.3526(e) on the Commission's Web site, with the exception of letters and emails from the public as required by 47 CFR 73.3526(e)(9), which will be retained at the station. A station must also link to the public inspection file hosted on the Commission's Web site from the home page of its own Web site, if the station has a Web site. The Commission will automatically link the following items to the electronic version of all licensee and applicant public inspection files, to the extent that the Commission has these items electronically: authorizations, applications, contour maps; ownership reports and related materials; portions of the Equal Employment Opportunity file held by the Commission; the public and broadcasting; Children's television programming reports; and DTV transition education reports.

Pursuant to 47 CFR 73.3527(b) non-commercial educational television station licensees or applicants must place the contents of their public inspection file as required by 47 CFR 73.3527(e) on the Commission's Web site. A station must also link to the public inspection file hosted on the Commission's Web site from the home page of its own Web site, if the station has a Web site. The Commission will automatically link the following items to the electronic version of all licensee and applicant public inspection files, to the extent that the Commission has these items electronically: contour maps; ownership reports and related materials; portions of the Equal Employment Opportunity file held by the Commission; and the public and broadcasting.

OMB Control Number: 3060–0174.

Title: Sections 73.1212, 76.1615 and 76.1715, Sponsorship Identification.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Parties: Business or other for profit entities; Individuals or households.

Number of Respondents and Responses: 22,761 respondents and 1,831,610 responses.

Estimated Time per Response: .0011 to .2011 hours.

Frequency of Response: Recordkeeping requirement; Third party disclosure; On occasion reporting requirement.

Total Annual Burden: 242,633 hours.

Total Annual Cost: $33,828.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in sections 4(i), 317 and 507 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: The FCC is preparing a system of records, FCC/MB–2, ''Broadcast Station Public Inspection Files,'' to cover the personally identifiable information (PII) that may be included in the broadcast station public inspection files. Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Privacy Impact Assessment(s): The FCC is preparing a PIA.

Needs and Uses: The Commission is seeking final approval of the information collection requirements that were adopted in FCC 12–44 and contained in collection 3060–0174 from the Office of Management and Budget (OMB). On April 27, 2012, the Commission released a Second Report and Order, MB Docket Nos. 00–168 and 00–44; FCC 12–44. This Second Report and Order adopted information collection requirements that will change the availability of record disclosures under 47 CFR 73.1212. 47 CFR 73.1212(e) states that, when an entity rather than an individual sponsors the broadcast of matter that is of a political or controversial nature, the licensee is required to retain a list of the executive officers, or board of directors, or executive committee, etc., of the organization paying for such matter in its public file.

The information collection requirements consist of:

Pursuant to the changes contained in 47 CFR 73.1212(e), this list, which could contain personally identifiable information, would be located in a public file to be located on the Commission's Web site instead of being maintained in the public file at the station. Burden estimates for this change are included in OMB Control Number 3060–0214.

Federal Communications Commission.

Bulah P. Wheeler,

Deputy Manager, Office of the Secretary, Office of Managing Director.

[FR Doc. 2012–11435 Filed 5–10–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update Listing of Financial Institutions in Liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as ''of record'' notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: May 7, 2012.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC Ref. No.	Bank name	City	State	Date closed
10439	Security Bank, National Association	North Lauderdale	FL	5/4/2012

[FR Doc. 2012–11330 Filed 5–10–12; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: May 16, 2012—10:00 a.m.

PLACE: 800 North Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The meeting will be held in Open Session.

MATTERS TO BE CONSIDERED:

1. Briefing on Committee on the Marine Transportation System (CMTS).
2. Briefing on XXI Latin American Congress of Ports.
3. Staff Briefing on Service Contracts that Reference Freight Indices.
4. Briefing and Discussion of Potential Notice of Inquiry Regarding Container Freight Indices for U.S. Agricultural Export Commodities.
5. Docket No. 11–22: Staff Recommendation and Draft Direct Final Rule on Revisions to Part 532, Non-Vessel-Operating Common Carrier Negotiated Rate Arrangements.

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523–5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2012–11674 Filed 5–9–12; 4:15 pm]

BILLING CODE 6730–01–P

FEDERAL TRADE COMMISSION

[File No. 121 0014]

Kinder Morgan, Inc. and El Paso Corporation; Analysis of Proposed Agreement Containing Consent Orders To Aid Public Comment; Correction

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement; correction.

SUMMARY: The Federal Trade Commission published a document in the **Federal Register** of May 7, 2012, requesting public comments on an analysis of proposed consent orders to aid public comment. The document contained an incorrect date.

FOR FURTHER INFORMATION CONTACT: Philip M. Eisenstat (202–326–2769), FTC, Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

Correction

In the **Federal Register** of May 7, 2012, in FR Doc. 2012–10870, on page 26760, the third column, first paragraph, correct the date to receive public comments to read ''June 4, 2012.''

Donald S. Clark,

Secretary.

[FR Doc. 2012–11379 Filed 5–10–12; 8:45 am]

BILLING CODE 6750–01–P

GOVERNMENT ACCOUNTABILITY OFFICE

Health Information Technology Policy Committee Vacancy

AGENCY: Government Accountability Office (GAO).

ACTION: Notice on letters of nomination to fill vacancy.

SUMMARY: The American Recovery and Reinvestment Act of 2009 (ARRA) established the Health Information Technology Policy Committee (Health IT Policy Committee) and gave the Comptroller General responsibility for appointing 13 of its 20 members. ARRA requires that 3 members be advocates for patients or consumers. Due to a vacancy on the Committee, GAO is accepting nominations of individuals to fill one of these three positions. For this appointment I am announcing the following: Letters of nomination and resumes should be submitted between May 5 and 25, 2012 to ensure adequate opportunity for review and consideration of nominees.

ADDRESSES:

GAO: *HITCommittee@gao.gov.*

GAO: 441 G Street NW., Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: GAO: Office of Public Affairs, (202) 512–4800. 42 U.S.C. 300jj–12.

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2012–10823 Filed 5–10–12; 8:45 am]

BILLING CODE 1610–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12–12BO]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Monitoring and Reporting System for Community Transformation Grant Awardees—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Community Transformation Grant (CTG) program facilitates the implementation, evaluation, and dissemination of evidence-based community preventive health activities that reduce the public health burden of chronic diseases. The program was authorized by the Prevention and Public Health Fund (PPHF) of the Patient Protection and Affordable Care Act of 2010 (ACA), and emphasizes five strategic areas: Tobacco-free living, active living and healthy eating, high impact evidence-based clinical and other preventive services, social and emotional wellness, and a healthy and safe physical environment. The CTG program is administered by the Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

In September 2011, CDC awarded 68 CTG cooperative agreements to state and local governmental agencies, tribes and territories, state or local non-profit organizations, and national networks of community-based organizations. Fifty-four awardees were from state, local and tribal government, and 14 awardees were from the private, non-profit sector. Each awardee is charged with implementing a work plan that will lead to specific, measurable health outcomes in its jurisdiction or service area. The evaluation strategy for the CTG requires awardees to define their objectives in a format that is specific, measurable, achievable, relevant and time-framed (SMART).

CTG awardees are required to provide semi-annual reports to CDC that describe and update their work plans, objectives, partnerships, resources, and activities. CDC will collect the information through a web-based electronic management information system (MIS). CDC conducted initial population of the MIS for the current 68 awardees. For routine, semi-annual reporting, the average burden is estimated at three hours per response. Burden for current CTG awardees is estimated solely on the basis of the required semi-annual reports.

If CDC receives funding to support additional CTG program awards, CDC will submit a Change Request to OMB that updates the list of CTG awardees and the total estimated annualized burden hours. New CTG awardees will be responsible for initial population of their MIS information. The estimated burden for each additional CTG awardee will include a one-time adjustment of 15 hours for initial population of their MIS information, in addition to the burden associated with routine semi-annual reporting.

The MIS will be used to satisfy CTG awardees' routine reporting requirements, monitor awardee progress, identify needs for targeted technical assistance, and respond to inquiries about the CTG initiative from the Department of Health and Human Services (HHS), the White House, Congress and other sources. CDC's collection of this information is authorized by section and sections 311 and 317(k)(2) of the Public Health Service Act, 42 U.S. Code 243 and 247b(k)2.

OMB approval is requested for three years. There are no costs to respondents other than their time. Based on the current 68 CTG awardees, the total estimated annualized burden hours are 408, including both public and private sector awardees.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Community Transformation Grant Awardees (state, local and tribal government sector)	54	2	3
CTG Awardees (private sector)	14	2	3

Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–11090 Filed 5–10–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Time and Date: 8:30 a.m.–5 p.m., June 6, 2012.

Place: Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018, Telephone (859) 334–4611, Fax (859) 334–4619.

Status: Open to the public, but without an oral public comment period. To access by conference call dial the following information 1 (866) 659–0537, Participant Pass Code 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2013.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Discussed: The agenda for the Subcommittee meeting includes: discussion of dose reconstruction cases under review (sets 7–9 and claims with Category A findings from sets 10–13); dose reconstruction quality management and assurance activities, including overview of contractor quality management and internal dose reconstruction blind reviews; dose reconstruction issues from NIOSH 10-year review, including review of resource impact of possible changes to efficiency process and plans for claimant favorability analysis.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Contact Person for More Information: Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email *ocas@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 4, 2012.

Cathy Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–11388 Filed 5–10–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis Meeting (ACET)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Time and Date: 11:00 a.m.–3:30 p.m., June 5, 2012.

Place: This meeting is accessible by Web conference. Toll-free +1 (800) 369–1742, Toll +1 (517) 308–9167; Participant Code: ACET 2012. For Participants: URL: *https://www.mymeetings.com/nc/join/*.

Conference number: PW5343563.

Audience passcode: ACET 2012.

Participants can join the event directly at: *https://www.mymeetings.com/nc/join.php?i=PW5343563&p=ACET%202012&t=c.*

Status: Open to the public limited only by Web conference. Participation by Web conference is limited by the number of 150 ports available.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Discussed: Agenda items include the following topics: (1) Developing a 3–5 year Strategic Plan for ACET; (2) Modeling TB Epidemiology; (3) Tuberculosis Outbreaks in Special Populations; (4) The Restructuring of United States Tuberculosis Program (TRUST)—How to Manage Budget Cuts; and (5) other tuberculosis-related issues.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Margie Scott-Cseh, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., M/S E–07, Atlanta, Georgia 30333, telephone (404) 639–8317; Email: *zkr7@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 4, 2012.

Cathy Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–11405 Filed 5–10–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates: 8:00 a.m.–5:00 p.m., June 21, 2012 (Closed). 8:00 a.m.–5:00 p.m., June 22, 2012 (Closed).

Place: Hilton, 333 O'Farrell Street, San Francisco, CA 94102, Telephone (415) 771–1400, Fax (415) 923–5036.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters To Be Discussed: The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and

occupational health-related grant applications.

These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, Ph.D., NIOSH Health Scientist, 2400 Executive Parkway, Mailstop E–20, Atlanta, Georgia 30345, telephone 404.498.2511, fax 404.498.2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 4, 2012.

Cathy Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–11401 Filed 5–10–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–643 and CMS–10425]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection. *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations. *Use:* CMS uses the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the Hospice Survey and Deficiencies Report Form is coded for entry into the OSCAR system. The data is analyzed by the CMS regional offices and by the CMS central office components for program evaluation and monitoring purposes. The information is also available to the public upon request. *Form Number:* CMS–643 (OCN 0938–0379). *Frequency:* Yearly. *Affected Public:* State, Local, or Tribal Governments. *Number of Respondents:* 3,644. *Total Annual Responses:* 1,217. *Total Annual Hours:* 1,217. (For policy questions regarding this collection contact Kim Roche at 410–786–3524. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Evaluation of Patient Satisfaction and Experience of Care for Medicare Beneficiaries with End-Stage Renal Disease (ESRD): Impact of the ESRD Prospective Payment System (PPS) and ESRD Quality Incentive Program (QIP); *Use:* The Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) required the Secretary of HHS to submit to Congress a report detailing the elements and features for the design and implementation of a bundled ESRD PPS, specifying that such a system should include the bundling of separately billed drugs, clinical laboratory tests, and other items ''to maximum extent feasible''. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) directed the Secretary of HHS to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The ESRD PPS combines composite rate dialysis services with separately billable services under a single payment adjusted to reflect patient differences in resource needs or case-mix. The MIPPA also stipulated the development of quality incentives for the ESRD program. CMS has established the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) to address this provision of the legislation.

In order to assess the impact of the Final Rule on ESRD beneficiary experiences, satisfaction, and health outcomes, CMS is requesting OMB approval to conduct data collection to obtain input on the effect of the Final Rule on our ESRD beneficiaries. The purposes of this data collection effort are to assess beneficiary satisfaction and experience of care in terms of access to services, quality of care, outcomes, and cost. This will be measured through telephone surveys with ESRD beneficiary and through interviews with key stakeholder in the renal health care community. The information obtained from both the beneficiary respondents and key stakeholders will be used both to provide an initial reporting of the ESRD PPS/QIP's effects on beneficiary satisfaction and experience of care and to inform the Centers for Medicare & Medicaid Services (CMS) of the impact of the ESRD PPS/QIP on patient satisfaction and experience of care, including unintended consequences, for consideration of future modification of the programs.

Form Number: CMS–10425 (OCN: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals. *Number of Respondents:* 2,540. *Number of Responses:* 2,540. *Total Annual Hours:* 1,287. (For policy questions regarding this collection contact Steve Blackwell at 410–786–6852. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *July 10, 2012:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic

Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 8, 2012.

Martique Jones,

Director, Regulations Development Group, Division B Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–11441 Filed 5–10–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8050–N]

Medicare Program; Meeting of the Medicare Economic Index Technical Advisory Panel—May 21, 2012

Correction

In notice document 2012–10702 appearing on pages 26553–26554 in the issue of Friday, May 4, 2012 make the following corrections:

1. On page 26553, in the third column, in the last paragraph on the page ''III. Registration Instructions'', the third sentence should appear as set forth below:

''You may register online at *http://www.hcdi.com/mei/* or by phone by contacting Toya Via, HCD International, at (301) 552–8803, by 5:00 p.m. EDT, Monday, May 14, 2012.''

[FR Doc. C1–2012–10702 Filed 5–10–12; 8:45 am]

BILLING CODE 1501–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Understanding Urban Indians' Interactions with ACF Programs and Services.

OMB No.: New Collection.

Description: As part of the ''Understanding Urban Indians' Interactions with ACF Programs and Services'' research study, telephone interviews will be conducted with up to 34 directors of Urban Indian Centers around the county, and site visits will be made to four urban areas with a high percentage of American Indians or Alaska Natives within the population: Phoenix, AZ; New York City, NY; Minneapolis, MN; and Anchorage, Alaska. Members of the research study team will utilize a telephone interview guide and field discussion guide to collect information from staff members at relevant programs and organizations (*e.g.,* American Indian Organizations, social service agencies serving urban Indians) in these areas.

The goal of this information collection is to assess the challenges and context for family self-sufficiency for urban Indians and their interaction with services and programs offered by ACF. The information gathered will help to generate recommendations and action items for ACF in seeking to better understand and meet the needs of the urban Indian population.

Respondents: Urban Indian Center directors, non-Native service providers, Native service providers, and AI/AN residents.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Telephone interview guide for directors of Urban Indian Centers	34	1	1.25	42.5
Interview guide for Native service providers	24	1	1	24
Interview guide for non-Native service providers	24	1	1	24
Interview guide for AI/AN residents of CITY	64	1	1	64

Estimated Total Annual Burden Hours: 154.5.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2012–11273 Filed 5–10–12; 8:45 am]

BILLING CODE 4184–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of the Award of a Single-Source Program Expansion Supplement to Pima County Community College District in Tucson, AZ

AGENCY: Office of Family Assistance, ACF, HHS.

ACTION: Award of a Single-Source Program Expansion Supplement to Pima County Community College District, a public/state controlled institution of higher education in Tucson, Arizona.

CFDA Number: 93.093.

Statutory Authority: Section 2008(a) of Title XX of the Social Security Act, as amended by Section 5507 of the Affordable Care Act (Pub. L. 111–148).

SUMMARY: This Administration for Children and Families (ACF), Office of

Family Assistance (OFA), Health Profession Opportunity Grants (HPOG) program announces the award of a single-source program expansion supplement to Pima County Community College District (PCC), a public/state controlled institution of higher education in Tucson, Arizona. Expansion supplement funds will support the acceleration of enrollment in Project Year Two, necessitated by a random assignment study entitled—Innovative Strategies for Increasing Self-Sufficiency (ISIS). This allows PCC to meet the sample size required by ISIS in the specific time period.

PCC was found to be an ideal fit as an ISIS evaluation site due to its unique program characteristics. The program has a clear articulated career pathway program, capacity to achieve a treatment sample of 500 or more over two project years, and a treatment sample that would be clearly distinct from the control sample because of the provision of intensive support and HPOG specific classes that are contextualized and compressed.

DATES: The project period for the award is September 30, 2011–September 29, 2012.

FOR FURTHER INFORMATION CONTACT: Stan Koutstaal, Program Manager, Office of Family Assistance, 370 L'Enfant Promenade SW., Washington, DC 20447. Telephone: 202–401–5457; Email: *stanley.koutstaal@acf.hhs.gov.*

Earl S. Johnson,

Director, Office of Family Assistance.

[FR Doc. 2012–11489 Filed 5–10–12; 8:45 am]

BILLING CODE 4184–48–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0430]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Submission of Food/Feed Facility Profile Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's program of voluntary submission of food facility profile information and new Form FDA 3797, which may be submitted electronically via the FDA Industry Systems Web site.

DATES: Submit either electronic or written comments on the collection of information by July 10, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Submission of Food/Feed Facility Profile Information (OMB Control Number 0910—New)

FDA has broad legal authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Public Health Service Act to protect the public health and the safety of the nation's food supply. In addition, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) (the ''Bioterrorism Act'') FDA was further authorized to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The Bioterrorism Act added section 415 of the FD&C Act (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. FDA regulations at 21 CFR 1.230 through 1.235 set forth the procedures for registration of food (including animal food/feed) facilities. Information provided to FDA under these regulations helps us notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. Furthermore, the FDA Food Safety Modernization Act (Pub. L. 11–353) (FSMA) added section 421 of the FD&C Act (21 U.S.C. 350j), which directed FDA to allocate resources to inspect facilities according to the known safety risks of the facilities. We propose to collect additional food/feed facility profile information on a voluntary basis from firms that complete the FDA food facility registration process. Food facility profile information voluntarily provided to FDA will help us to determine whether a firm is high-risk or non-high-risk. We will use the profile information to assist us in determining the frequency at which we will inspect the firm. Facilities that voluntarily submit the food facility profile information would benefit from our advance preparation through interaction with better-informed investigators and potentially reduced inspection time. The need for this collection of information derives from our objective to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)).

Firms will be offered the opportunity to voluntarily complete a food/feed facility profile after they register with FDA using the electronic system known as the Food Facility Registration Module, which is available at *http://www.access.fda.gov,* the FDA Industry Systems Web site. The use of an electronic form would enhance our ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that we could target inspections to facilities that manufacture, process, or pack foods that are at increased risk for a food safety problem. After completing their registration process, firms will see a popup screen by which they will be able to navigate to the food facility profile screens to provide the profile information. Food and feed facility profile information will only be collected electronically in English.

Information we propose to request in the voluntary food and feed facility profile includes, among other things:

- The facility type (e.g., manufacturer/processor, repacker/packer, or warehouse/holding facility);
- The products, and hazards (e.g., biological, physical, chemical) and preventive control measures associated with those products where either there is a regulation in place requiring identification of hazards and preventive control measures, e.g., seafood and juice, or the firm as a matter of its own business practices voluntarily identifies hazards and implements preventive control measures; and
- Other facility information (e.g., food safety training, facility size, operational schedule, and number of employees).

Firms will be given the option of providing or updating their profile information whenever the firm accesses the Food Facility Registration Module (e.g., when completing their initial registration process or when updating their registration information). FDA will also provide a direct URL that a firm may use to submit the facility profile information at a time when they are not registering or updating their registration information.

Description of Respondents: The respondents to this information collection include owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of New Domestic Food Facility Profile.	FDA 3797	6,780	1	6,780	0.25 (15 minutes)	1,695
Submission of New Foreign Food Facility Profile.	FDA 3797	11,685	1	11,685	0.75 (45 minutes)	8,764
Submission of Update to Existing Food Facility Profile.	FDA 3797	59,265	1	59,265	0.0833 (5 minutes)	4,937
Total						15,396

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on our experience and the average number of new facility registrations and updates estimated in the notice published in the **Federal Register** of May 28, 2010 (75 FR 30033) (the May 2010 notice) during the most recent request for extension of OMB approval under the PRA for the FDA food facility registration process (approved under OMB control number 0910–0502). In the May 2010 notice, we estimated that the annual number of new domestic facility registrations will be 13,560. Assuming that approximately half of these firms will also choose to provide the food facility profile information, we estimate that 6,780 domestic firms will voluntarily submit Form FDA 3797 annually. We estimate that submitting the food facility profile information will require a burden of approximately 0.25 hour (15 minutes) per average domestic facility. Thus, the total annual burden for the submission of new domestic food facility profiles is estimated to be 1,695 hours (6,780 × 0.25 hour = 1,695 hours).

In the May 2010 notice, we estimated that the annual number of new foreign facility registrations will be 23,370. Assuming that approximately half of these firms will also choose to provide the food facility profile information, we estimate that 11,685 foreign firms will voluntarily submit Form FDA 3797 annually. We estimate that submitting the food facility profile information will require a burden of approximately 0.75 hour (45 minutes) per average foreign facility, taking into account that for some foreign facilities the respondent completing the registration may not be fluent in English. The information must be submitted electronically in the English language. Thus, the total annual burden for the submission of new foreign food facility profiles is estimated to be 8,764 hours (11,685 × 0.75 hour = 8,763.75 rounded to 8,764 hours).

In the May 2010 notice, we estimated that we will receive 118,530 registration updates annually. Assuming that approximately half of these firms will also choose to update their food facility profile information, we estimate that 59,265 firms will voluntarily submit Form FDA 3797 for that purpose annually. FDA estimates that updating food facility profile information will require a burden of approximately 0.0833 hour (5 minutes) per average facility, taking into account fluency in English. Thus, we estimate the total annual burden for updating food facility profiles to be 4,937 hours (59,265 × 0.0833 hour = 4,936.77 rounded to 4,937 hours).

We recognize that the May 2010 notice was issued prior to the passage of FSMA, which was signed into law on January 4, 2011. Section 102(a) of FSMA amended section 415 of the FD&C Act to create section 415(a)(3) (21 U.S.C. 350d(a)(3)), which requires that during the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has previously registered shall submit a renewal registration. We anticipate that this provision will impact the number of firms that access the Food Facility Registration Module and that are therefore given the option of providing or updating their profile information. Estimates regarding the impact of section 415(a)(3) will be provided in our next request for extension of OMB

approval under the PRA for the FDA food facility registration process (approved under OMB control number 0910–0502).

Dated: May 8, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–11457 Filed 5–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program FY 2012 Non-Competing Continuation Progress Report (OMB No. 0915–xxxx)—[New] Activity Code: X02

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA). Section 2951 of the Act amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant, and Early Childhood Home Visiting Program, (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf,* pages 216–225). The Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs.

Under this program, $125,000,000 was made available to States on a formula basis in both FY 2010 and 2011. This funding was awarded to support States in implementing their Updated State Plans. Additionally, a competitive funding opportunity announcement (FOA) was issued in June 2011 to allow interested States to apply for one of two possible grants: Development Grants and Expansion Grants. Development Grants are intended to support States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity needed to seek an Expansion Grant in the future. Expansion Grants are intended to recognize States and jurisdictions that had already made significant progress towards a high-quality home visiting program or embedding their home visiting program into a comprehensive, high-quality early childhood system. Thirteen States were awarded Development Grants, and nine States were awarded Expansion Grants. State grantees of both competitive programs will need to complete non-competing continuation (NCC) progress reports in order to secure the release of FY 2012 and out-year grant funds.

The MIECHV Program intends to make approximately $125,000,000 in formula-based funds available to States and jurisdictions in FY 2012 subsequent to the completion of FY11 Progress Reports. The project period is 2 years.

The annual estimate of burden is as follows:

Instrument: A summary of the progress on the following activities	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Accomplishments and Barriers	54	1	2	108
Program Goals and Objectives	54	1	8	432
Update on Evaluation Plan	54	1	4	216
Implementation in Targeted At-Risk Communities	54	1	24	1296
Progress on Benchmark Reporting	54	1	6	324
CQI efforts	54	1	4	216
Program Administration	54	1	4	216
Total	54			2808

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 3, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–11335 Filed 5–10–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Non-Competitive One-Year Extension With Funds for State Early Childhood Comprehensive Systems Grantees

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of a Non-Competitive One-Year Extension With Funds for State Early Childhood Comprehensive Systems (ECCS) (H–25) Grantees.

SUMMARY: The Health Resources and Services Administration (HRSA) will be issuing a non-competitive one-year extension with funds for the current grantees of the State Early Childhood Comprehensive Systems Program. Up to $150,000 per grantee will be awarded over a one-year extended project period. The State Early Childhood Comprehensive Systems (ECCS) Grant Program ensures the healthy physical, social, and emotional development of children (birth to five years of age) by supporting statewide collaborations of early childhood service providers to create a seamless system of early childhood services for young children and their families. Each ECCS grantee is an active member, and in some cases these grantees hold a leadership role in their early childhood multi-agency State teams. Together, such teams have developed Early Childhood Comprehensive Systems Plans that guide the development, implementation, governance, and financing of their States' early childhood service systems. The State team activities associated with these plans, and the comprehensive systems they describe, also include the identification and implementation of early childhood systems best-practice models, as well as the development of human resources and policies to support these practices. This extension with funds will allow HRSA's Maternal and Child Health Bureau (MCHB) to align its early childhood systems-building activities with HRSA's Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program, the State Advisory Councils (SACs) and other early childhood initiatives under the Administration for Children and Families (ACF), the Substance Abuse and Mental Health Services Administration's (SAMHSA) Project LAUNCH, and the Department of Education's Race to the Top (RTT).

SUPPLEMENTARY INFORMATION: Grantees of record and intended award amounts are:

Grantee organization name	Grant No.	State	FY2011 authorized funding level	FY2012 estimated funding level
Alabama department of public health	H25MC00238C0	AL	$150,000.00	$150,000.00
Arizona Early Childhood Development and Health Board	H25MC17140A0	AZ	150,000.00	150,000.00
Arkansas Department of Health	H25MC00265C0	AR	150,000.00	150,000.00
California Department of Public Health	H25MC08762B0	CA	150,000.00	150,000.00
Colorado State Department/Public Health & Environment	H25MC00228C0	CO	150,000.00	150,000.00
Commonwealth of the Northern Mariana Islands	H25MC06112B0	MP	150,000.00	150,000.00
Delaware Health & Social Services	H25MC00253C0	DE	150,000.00	150,000.00
District of Columbia/Department of Health	H25MC00241C0	DC	150,000.00	150,000.00
Florida State Department of Health	H25MC01320C0	FL	150,000.00	150,000.00
Georgia Department of Community Health	H25MC16260A0	GA	150,000.00	150,000.00
Idaho State Department of Health and Welfare	H25MC00245C0	ID	150,000.00	150,000.00
Illinois Department of Human Services	H25MC00247C0	IL	150,000.00	150,000.00
Indiana State Department of Health	H25MC00263C0	IN	150,000.00	150,000.00
Iowa Department of Public Health	H25MC00230C0	IA	150,000.00	150,000.00
Kansas State Department of Health and Environment	H25MC00234C0	KS	150,000.00	150,000.00
Kentucky Cabinet for Health Services	H25MC00255C0	KY	150,000.00	150,000.00
Louisiana State Department of Health & Hospitals	H25MC00271C0	LA	150,000.00	150,000.00
Maine Department of Human Services	H25MC00266C0	ME	150,000.00	150,000.00
Maryland Department of Health & Mental Hygiene	H25MC00273C0	MD	150,000.00	150,000.00
Massachusetts Department of Public Health	H25MC00262C0	MA	150,000.00	150,000.00
Michigan Department of Community Health	H25MC00252C0	MI	150,000.00	150,000.00
Minnesota Department of Health	H25MC00276C0	MN	150,000.00	150,000.00
Missouri Department of Health	H25MC01327C0	MO	150,000.00	150,000.00
Montana Department of Public Health and Human Services	H25MC06098B0	MT	150,000.00	150,000.00
North Carolina Department of Health and Human Services	H25MC00259C0	NC	150,000.00	150,000.00
Nevada Department of Human Resources	H25MC00229C0	NV	150,000.00	150,000.00
New Jersey State Department of Health and Senior Services	H25MC00248C0	NJ	150,000.00	150,000.00
New Mexico State Department of Health	H25MC00236C0	NM	150,000.00	150,000.00
New York State Office of Children and Family Services	H25MC12970A0	NY	150,000.00	150,000.00
North Dakota State Department of Health	H25MC00237D0	ND	150,000.00	150,000.00
Oklahoma State Department of Health	H25MC01323C0	OK	150,000.00	150,000.00
Oregon State Department of Human Services	H25MC00269C0	OR	150,000.00	150,000.00
Puerto Rico Department of Health	H25MC00274C0	PR	150,000.00	150,000.00
Republic of Palau Bureau of Health Services	H25MC00277C0	PW	150,000.00	150,000.00
State of Alaska Department of Health & Social Services	H25MC01326C0	AK	150,000.00	150,000.00
State of Connecticut	H25MC01329C0	CT	150,000.00	150,000.00
State of Hawaii Department of Health	H25MC00278C0	HI	150,000.00	150,000.00
State of Nebraska	H25MC00240C0	NE	150,000.00	150,000.00
State of New Hampshire	H25MC00249C0	NH	150,000.00	150,000.00
State of Ohio-Department of Health	H25MC01324C0	OH	150,000.00	150,000.00
State of Rhode Island Department of Health	H25MC00270C0	RI	150,000.00	150,000.00
State of South Carolina	H25MC06113B0	SC	150,000.00	150,000.00
Tennessee State Department of Health	H25MC00260C0	TN	150,000.00	150,000.00
Texas Health & Human Services Commission	H25MC03383C0	TX	150,000.00	150,000.00
University of Guam	H25MC18121A0	GU	150,000.00	150,000.00
Utah Department of Health	H25MC00268C0	UT	150,000.00	150,000.00
Vermont State Department of Health	H25MC00235C0	VT	150,000.00	150,000.00
Virginia State Department of Health	H25MC00231C0	VA	150,000.00	150,000.00
Washington State Department of Health	H25MC00254C0	WA	150,000.00	150,000.00
West Virginia, Department of Health and Human Services	H25MC01328C0	WV	150,000.00	150,000.00

Grantee organization name	Grant No.	State	FY2011 authorized funding level	FY2012 estimated funding level
Wisconsin State Department of Health & Social Services	H25MC00232C0	WI	150,000.00	150,000.00
Wyoming State Department of Health	H25MC00256C0	WY	150,000.00	150,000.00

Amount of the Award(s): Up to $150,000 per grantee over a one-year project period.

CFDA Number: 93.110.

Current Project Period: 6/1/2011 through 5/31/2012.

Period of Supplemental Funding: 6/1/2012 through 5/31/2013.

Authority: Title V, Section 501(a)(3) of the Social Security Act.

Justification

HRSA is extending funding for the ECCS grants by one year for the following reasons. MCHB has been working with leaders within HRSA involved in early childhood service systems, as well as with other early childhood experts and leaders in the field, to align its early childhood systems-building activities with early childhood investments within HRSA, including the MIECHV program, and with other Federal Government early childhood initiatives. HRSA/MCHB is focusing on the most efficient and effective use of funds to continue promoting coordinated, comprehensive early childhood systems and services for the Nation's children and families.

HRSA's MIECHV program funds evidence-based home visiting programs in 54 States and jurisdictions. Research shows that the success of such home visiting programs is dependent upon the kind of sound infrastructure that ECCS promotes and sustains. To ensure coordinated and non-duplicative HRSA program planning, as well as future early childhood systems programming, it is crucial to sustain MCHB's current systems development efforts under ECCS for one additional year while the next early childhood systems program is developed with input from stakeholders.

FOR FURTHER INFORMATION CONTACT: Audrey Yowell, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 10–86, Rockville, Maryland 20857 or email *ayowell@hrsa.gov.*

Dated: May 2, 2012.

Mary K. Wakefield,

Administrator.

[FR Doc. 2012–11377 Filed 5–10–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Center Core Grants.

Date: June 28, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue NW., Washington, DC 20009.

Contact Person: Richard D. Crosland, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–594–0635, *Rc218u@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group, Neurological Sciences and Disorders B.

Date: June 28, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, *neuhuber@ninds.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: May 4, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11506 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, NIDDK Ancillary R01 Telephone Review.

Date: June 13, 2012.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, NIDDK Member Conflict Telephone SEP.

Date: June 22, 2012.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 7, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11509 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: June 12, 2012.

Closed: 8:00 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, National Institute on Minority Health and Health Disparities, 6707 Democracy Blvd., Rm. 849, Bethesda, MD 20892.

Open: 9:30 a.m. to 5:00 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's Report, NIH Health Disparities update, and other business of the Council.

Place: National Institutes of Health, National Institute on Minority Health and Health Disparities, 6707 Democracy Blvd., Rm. 849, Bethesda, MD 20892.

Contact Person: Donna Brooks, Executive Officer, National Institutes of Health, National Institute on Minority Health and Heath Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 435–2135, *brooksd@ncmhd.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: May 7, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11510 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, NIBIB P41 Site Visit (2012/10).

Date: July 25–27, 2012.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Vanderbilt, 1811 Broadway, Nashville, TN 37203.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 960, Bethesda, MD 20892, 301–496–8775, *grossmanrs@mail.nih.gov*.

Dated: May 7, 2012.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–11507 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of National Eye Institute Participation in PA–11–347, ''NINDS SBIR Technology Transfer (SBIR–TT [R43/R44])''

This notice is intended to inform potential applicants that the National Eye Institute (NEI) is participating in *PA–11–347,* ''NINDS SBIR Technology Transfer (SBIR–TT [R43/R44]).'' The NEI seeks SBIR applications for projects to transfer technologies out of the NIH intramural research labs into the private sector that address mechanisms, diseases, or disorders within the NEI mission.

Any project that fits within the NEI mission and relies on the use of an NIH intramural technology is eligible for this award. Please see the NEI technology transfer Web site for more details on NEI licensing opportunities: *http://www.nei.nih.gov/resources/technologytransfer.asp.*

For a complete listing of NIH intramural technologies which are available, please see NIH Office of Technology Transfer at: *http://www.ott.nih.gov/Technologies/AbsSearchBox.aspx.*

The NEI Division of Intramural Research performs high quality and innovative research in a variety of basic, translational, and clinical areas,

including imaging, diagnostics, regenerative medicine, genetics/genomics, developmental biology, cellular and gene therapy, and cell and molecular biology related to eye health and eye disease treatments. For more information about the research and investigators in the NEI Division of Intramural Research, please see: *http://www.nei.nih.gov/intramural/.*

An NEI intramural investigator may provide assistance in a collaborative manner by providing technology, reagents and/or discussions during the SBIR award period; however, no SBIR funds are allowed to go to the NIH intramural investigator or the NIH intramural program.

All other aspects of the Funding Opportunity Announcement (FOA) remain unchanged.

Inquiries:

SBIR contact: Jerome Wujek, Ph.D., 5635 Fishers Lane; MSC 9300, Bethesda, MD 20892, (301) 451–2020, *wujekjer@nei.nih.gov*.

Licensing contact: Alan E. Hubbs, Ph.D., 6120 Executive Blvd., Bethesda, MD 20892, (301) 594–4263, *hubbsa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: April 30, 2012.

David Whitmer,

Executive Officer, NEI, National Institutes of Health.

[FR Doc. 2012–11512 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information Regarding the NIH-Industry Program To Discover New Therapeutic Uses for Existing Molecules

SUMMARY: As part of a larger initiative to help reengineer the process of translating scientific discoveries into new therapies, the recently established National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) will be launching a new collaborative program to support the exploration of promising drug candidates (compounds and biologics) across a broad range of human diseases. As an initial effort, the program will focus on discovering new therapeutic uses of existing molecules (Therapeutics Discovery).

The NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules is designed to be carried out through collaborations between pharmaceutical companies and the biomedical research community. The Program will match drug candidates and associated data from participating companies with the best ideas for new therapeutic uses put forward by the biomedical research community.

NCATS will be initiating this innovative concept as a limited pilot Program. If the pilot is successful, and depending on the level of interest and available funds, the Program may be expanded. To gauge the breadth and depth of potential interest in the Program and to obtain stakeholder input and perspectives on its novel features, NCATS is seeking input from the biomedical research community, prospective industry collaborators, and other members of the public on all aspects of the Program and more broadly on how the government can partner with the private sector in this area.

DATES: Comments in response to this notice are requested by June 1, 2012. The NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules funding announcement will be published in early June, 2012 in the NIH Guide to Grants and Contracts at *http://grants.nih.gov/grants/guide/index.html.*

FOR FURTHER INFORMATION CONTACT: Questions may be submitted electronically to *Therapeutics.Discovery@nih.gov.* For additional information, please contact Dr. Heng Xie, NCATS, at *XieHe@mail.nih.gov* or 301–443–8063.

SUPPLEMENTARY INFORMATION:

Background

On December 23, 2011, Congress created NCATS, (Pub. L. 112–74 passed December 23, 2011, amending the Public Health Service Act, 42 U.S.C. 287). One aspect of the NCATS mission focuses on developing innovative strategies, methods, and tools to reduce or eliminate barriers to drug and diagnostic development. By developing new methods that can be adopted across the entire medical product development sector, NCATS will enhance the capabilities of other sectors to bring safe and effective products to patients.

One of the strategies that NCATS will be pursuing is to advance research and development (R&D) efforts to find uses for therapeutics different from those for which they were originally developed (Therapeutics Discovery). Many discontinued compounds and biologics that have already been tested in human subjects may have promising applications for other indications and many approved drugs may be put to new uses. Harnessing previous R&D efforts and building on data already gathered may be a way to speed the testing of new clinical hypotheses and bring forward new treatments for a range of human diseases. Along with opportunities, however, there are also scientific, economic, and administrative challenges that need to be addressed. These were explored in an April 2011 Roundtable with senior leaders and experts from the pharmaceutical industry, government, academia, and the non-profit sector (*http://www.ncats.nih.gov/files/exploring_new_uses_for_abandoned_and_approved_therapeutics.pdf.pdf*). Some of the challenges identified at the Roundtable include: Resource implications (the time and resources for a pharmaceutical company to maintain, update, and organize their therapeutics libraries for investigating new therapeutic uses prior (drug rescue) or subsequent to (drug repurposing) FDA approval; patent considerations (off-patent or drugs whose patents are close to expiring may not be attractive to industry because the financial return and market incentives for the product may be limited); and transactional hurdles related to developing, negotiating and implementing appropriate legal agreements among the parties, including addressing such concerns as intellectual property rights and liability. The Roundtable participants concluded that because the private sector holds a substantial portion of the requisite assets, data, and knowledge and the public sector has new ideas and the wherewithal to advance new applications, public-private collaborations are central to rescue and repurposing efforts. Streamlining the initiation and execution of such partnerships will help promote collaboration, leverage the strengths of both sectors, and facilitate the formation of partnerships that are so critical to success.

NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules

The NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules Program is designed to be carried out through collaborations between pharmaceutical companies and investigators from the biomedical research community. The Program will match drug candidates and associated data from participating companies with the best ideas for new therapeutic uses put forward by the biomedical research community. Funded investigators will

work to validate novel human mechanisms of disease using drug candidates that have been made available by pharmaceutical companies for use in small interventional clinical validation studies. The Program will be initiated as a limited pilot, (see: *http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/therapeutic-uses.html*), which if successful and depending on availability of funding, may be expanded as to number of participating pharmaceutical companies, number of drugs candidates, areas of interest, and number of projects.

NCATS is currently engaging industry partners to develop a framework under which they will agree to provide drug candidates and partner with potential funding recipients under a pre-negotiated ''Collaborative Research Agreement'' that NCATS anticipates will be executed between each funding recipient and industry partner.

NCATS will be soliciting grant applications from investigators interested in working with a participating company to carry out studies of the company's drug candidate. The Request for Applications will be published in early June in the NIH Guide to Grants and Contracts (*http://grants.nih.gov/grants/guide/index.html*). Each company participating in the Program will have signed a Memorandum of Understanding with NCATS that articulates the goals and general terms of the Program. NCATS also anticipates that applicants will use template agreements (the Collaborative Research Agreement discussed above and a Confidential Disclosure Agreement, to formalize the relationship between the pharmaceutical partner and the biomedical investigator's institution. The template agreements will help streamline interactions among the parties, expediting the initiation of the discovery efforts. The template agreements are available for comment at: *http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/agreements.htm.*

NCATS will use a two-stage application process to identify meritorious projects and a cooperative agreement mechanism to fund the research. The first step in the process is the submission of a pre-application, called an X02. The second step is submission of a full application using a funding mechanism that can be used for clinical research known as UH2/UH3 or stand-alone UH3. Information on the drug candidates such as the drug's mechanism of action and any limitations in use based on the toxicological profile will be available when the X02 funding opportunity announcement is published in the NIH Guide. Investigators who submit pre-applications will be expected to demonstrate that they have the requisite competencies, capabilities, creativity, and environment necessary to carry out clinical trials as well as any necessary pre-clinical studies to provide evidence a drug candidate could target critical biological processes in a new disease area. The pre-application will be peer reviewed. Submitters of the most meritorious of the pre-applications will be invited to submit a full application for funding to conduct pre-clinical or non-interventional clinical studies (UH2) to provide sufficient confidence in the biological rationale for the new therapeutic use and clinical trials (UH3) in the new selected disease area using the drug candidate. The total project period will not exceed three years. Prior to the proposed clinical studies, investigators will be expected to submit an investigator-sponsored Investigational New Drug (IND) application to the Food and Drug Administration (FDA). More details about the funding mechanism and application process are published as NIH Notice of intent NOT–TR–12–001 in the NIH Guide for Grants and Contracts (*http://grants.nih.gov/grants/guide/notice-files/NOT-TR-12-001.html*). A Request for Information, NOT–TR–12–002, is also published in the NIH Guide for Grants and Contracts (*http://grants.nih.gov/grants/guide/notice-files/NOT-TR-12-002.html*).

Request for Information

To gauge the breadth and depth of potential interest in the Program and to obtain stakeholder input and perspectives on its novel features, NCATS is seeking input from the scientific community, potential industry collaborators, and other members of the public on all aspects of the Program. NCATS is particularly interested in but not limited to feedback on the following issues:

1. Partnerships with industry have been used throughout government and the biomedical research community to leverage each sector's expertise to speed scientific research and corresponding commercial development. We are interested in hearing about innovative strategies and practices that have proven successful to develop novel uses for discontinued Agents that have no known development limitations and are safe for use in humans. Your response can include your opinion of the most significant challenges for public-private partnerships that foster drug rescue between biomedical researchers and the pharmaceutical industry as well as your experiences with drug rescue or repurposing partnerships. Your input on options NCATS can consider which promise to nurture academic efforts to foster greater translation through projects such as the NIH–Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules. Your response can also include input on how NIH can identify partners that would like to provide drugs and biologics that are no longer being pursued internally to the NIH research community for investigation for new therapeutic uses.

2. Because this Program involves obtaining permission to use, and work with, privately owned Agents, exclusive patent or regulatory rights will likely be important incentives for the commercial success of the new therapeutic use for a drug candidate identified under the NIH–Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules. The ability to achieve an exclusive right to market a drug product, whether through a new use or other patentable subject matter related to the Agent, is likely to significantly affect the pharmaceutical partner's or other developer's incentive to commercialize rescued drugs or biologics based on new research results arising from the Program.

NCATS understands that a significant impediment to government, academic, non-profit, and industry partnerships involved in discovering and commercializing new uses of Agents is the ''transaction cost'' of negotiating appropriate legal agreements on a case-by-case basis. Thus, to address this concern, a key feature of the Program is that template agreements will be offered as a means of implementing the partnership. We are interested in the views of potential academic and industry partners on the transaction cost of developing individual agreements as well as the desirability of using template agreements and incorporating them into this Program. We are interested in your comments on how the use of template CDAs and CRAs in general and the current CDA and CRA might affect your institution's participation in the therapeutics discovery program. Applicants will be able to access these agreements prior to submitting an NIH X02 pre-application. For more details, please see Notice NOT–TR–12–001.

3. Comments on how working with a Clinical and Translational Science Award site (CTSAs) could advance drug rescue research projects, particularly for rare and neglected diseases.

4. Comments on how working with NIH Intramural Research Program

investigators (*http://www.irp.nih.gov*) and the NIH Clinical Center resources (*http://www.cc.nih.gov/index.html*) could advance your drug rescue research project.

5. Discussion of whether the goals and incentives of the NIH–Industry Program: Discovering New Therapeutic Uses for Existing Molecules are sufficient for biotechnology and pharmaceutical companies and the biomedical research community to participate in the Program. Discuss the most important steps NCATS should take to promote and facilitate partnerships for therapeutics discovery between industry and the biomedical research community. Your perspective on how success of the therapeutics discovery program might be defined.

6. Comments on the resources that a biotechnology or pharmaceutical company partner might realistically contribute to an NCATS program on therapeutics discovery in addition to the Agent and the associated data. You can also comment on the type of information about the molecules that you would be willing to disclose publicly.

7. Comments on the pharmacologic activity or biological target of the drug candidate that you need access to in order to test your biological hypothesis of disease intervention.

Comments in response to the topics above should be submitted to *http://grants.nih.gov/grants/rfi/therapeutics_discovery/index.cfm?ID=24* and will be accepted through June 1, 2012. Other questions or comments relevant to this initiative may be submitted to *Therapeutics.Discovery@nih.gov.*

Dated: May 7, 2012.

Thomas R. Insel,

Acting Director, NCATS, National Institutes of Health.

[FR Doc. 2012–11511 Filed 5–10–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Customs Modernization Act Recordkeeping Requirements

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing information collection.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Customs Modernization Act Record Keeping Requirements. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** (77 FR 13617) on March 7, 2012, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before June 11, 2012.

ADDRESSES: Interested persons are invited to submit written comments on this information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Customs Modernization Act Recordkeeping Requirements.

OMB Number: 1651–0076.

Form Number: None.

Abstract: The North American Free Trade Agreement Implementation Act, Title VI, known as the Customs Modernization Act (Mod Act) amended title 19 U.S.C. 1508, 1509 and 1510 by revising Customs and Border Protection (CBP) laws related to record keeping, examination of books and witnesses, regulatory audit procedures and judicial enforcement. Specifically, the Mod Act expanded the list of parties subject to CBP recordkeeping requirements, distinguished between records which pertain to the entry of merchandise and financial records needed to substantiate the correctness of information contained in entry documentation, and identified a list of records which must be maintained and produced upon request by CBP. The information and records are used by CBP to verify the accuracy of the claims made on the entry documents regarding the tariff status of imported merchandise, admissibility, classification/nomenclature, value and rate of duty applicable to the entered goods. The Mod Act recordkeeping requirements are provided for by 19 CFR part 163.

Action: CBP proposes to extend the expiration date of this information collection with a change to the burden hours as a result of a revised estimate of the number of respondents currently complying with these recordkeeping provisions. There are no changes to these recordkeeping requirements.

Type of Review: Extension (with change).

Affected Public: Businesses.

Estimated Number of Respondents: 5,459.

Estimated Number of Total Annual Responses: 5,459.

Estimated Time per Response: 1,040 hours.

Estimated Annual Burden Hours: 5,677,360.

Dated: May 8, 2012.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2012–11430 Filed 5–10–12; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Special Ops Flashlights and Sportsman Flashlights

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (''CBP'') has issued a final determination concerning the country of origin of a Special Ops Flashlight, Sportsman Flashlight, and a light-emitting diode (LED) blank assembly. Based upon the facts presented, CBP has concluded in the final determination that India is the country of origin of the blank LED Assembly, Special Ops Flashlight, and Sportsman Flashlight for purposes of U.S. Government procurement.

DATES: The final determination was issued on May 7, 2012. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within June 11, 2012.

FOR FURTHER INFORMATION CONTACT: Robert Dinerstein, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202–325–0132).

SUPPLEMENTARY INFORMATION: Notice is hereby given that on May 7, 2012, pursuant to subpart B of part 177, Customs and Border Protection (CBP) Regulations (19 CFR Part 177, Subpart B), CBP issued a final determination concerning the country of origin of the blank LED Assemblies, Special Ops Flashlights and Sportsman Flashlights which may be offered to the United States Government under an undesignated government procurement contract. This final determination, in HQ H185149, was issued at the request of Southwest Synergistic Solutions under procedures set forth at 19 CFR Part 177, Subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the Special Ops Flashlights and the Sportsman Flashlights which are assembled in the United States using the blank LED assemblies from India are products of India for purposes of U.S. Government procurement. The country of origin of the blank LED assembly is India.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: May 7, 2012.

Sandra L. Bell,

Executive Director, Regulations and Rulings, Office of International Trade.

H185149

May 7, 2012

CLA–2 OT:RR:CTF:VS H185149 RSD

CATEGORY: Marking

Mr. Juan Enrique-Cienfuegos
Southwest Synergistic Solutions
215 N. Center, # 703
San Antonio, Texas 78202

RE: Country of Origin of Special Ops Flashlights, Sportsman Flashlights, and Blank LEDs Assemblies

Dear Mr. Cienfuegos:

This letter is in response to your letter of July 12, 2011, to our National Commodity Specialist Division, in which you requested a binding ruling pertaining to the classification under the Harmonized Tariff Schedule of the United States (HTSUS) and the country of origin for marking and government procurement of three items, the special ops flashlight, sportsman flashlight and light-emitting diodes (LEDs) blank assemblies. Your letter was forwarded from our National Commodity Specialist Division (NCSD) in New York to this office for a response to your request for a ruling on the country of origin for government procurement. By separate emails sent from January 6 through 21, 2012, you provided additional information for consideration as part of your ruling request. Samples of the articles were enclosed for our consideration. The classification and country of origin marking issues will be dealt with under separate cover.

Under the pertinent regulations, which implement Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. § 2511 et seq.), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purpose of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of special ops flashlight, sportsman flashlight and LED blank assemblies. We note that Southwest Synergistic Solutions is a party-at-interest within the meaning of 19 CFR § 177.22(d)(1) and is entitled to request this final determination.

FACTS:

The imported product under consideration is a LED blank assembly. The LED blank assembly is sold to for hobbyists who want to create their own unique lights. The assembly can be made into two types of flashlights, the Special Ops Flashlight and the Sportsman Flashlight. The LED blank assemblies are cylindrical in shape and measure approximately 1⅜ inches tall with an outside diameter of 7/8 of an inch. The LED blank assemblies consist of multi-colored LEDs with Printed Circuit Boards (PCBs) attached to them. They incorporate four LEDs and a push-button switch that controls the LEDs. Both the LEDs and PCBs are made in India, where the two items are attached together. The power source used for the LED blank assemblies is a 3 volt lithium battery which is imported separately and sourced from China. The battery is attached to the LED blank in the United States. The remaining part that is attached to the LED blank assembly in the U.S. is the plastic battery tube. This is done by holding the PCB and outwardly folding the soldered battery straps to create a slight V shape; inserting the PCB into the battery tube; inserting the 3 V Lithium battery into the bottom side of the battery tube; sliding the battery back plate into place to close the circuit; and testing the LED blank.

You claim the LED assembly is a blank, which can be utilized for several types of lights including flashlights, signal lights, ornamental lights, or novelty lights. The LED illumination is directional and the boards are currently imported with four different LED control software programs. The PCB can be reprogrammed in the United States depending on the demand at the time for a particular version. Furthermore, the sequences can be customized based on the customer's desired settings.

Special Op Flashlight and Sportsman Flashlight

The LED assembly blanks may be used to produce two types of flashlights. The first product is a Special Ops Flashlight containing an infrared LED and 3 visible colored lights. The second flashlight contains visible colored lights and is called the Sportsman Flashlight. The various color wavelengths offer the user a variety of illumination options. The infrared LED is used by special forces or SWAT teams to illuminate maps or their walking path, and can only be seen with infrared night vision optics. The red light is used for low light illumination to preserve night vision equipment. The yellow light is used for low light illumination and animal watching. The green light is used for map reading. The blue light is used for fluid trail blood tracking. The Special Ops and Sportsman flashlight consists of the following components.

1. LED blank assemblies,
2. Silicon Flashlight top,
3. Silicon Ross bottomed magnetic end cap,
4. Magnets,
5. Packaging tube and cap, and
6. Instructions.

The assembly for both flashlights is as follows:

1. Select proper LED blank software version;
2. Insert LED blank into Silicon Flashlight top;
3. Place magnets inside Cross bottomed Magnetic end cap;
4. Attach the Silicon Cross bottomed magnetic end cap to assembled Silicon Flashlight light top;
5. Test for proper function;
6. Place the instructions inside packaging tube; and
7. Place the finished flashlight into the packaging tube and cover with top.

You indicate that all the software for the flashlights is written in the United States. The PCB's used in the LED blank assemblies produced in India will always be programmed with one version of the U.S. software. Some will have only one function programmed at the time of import and if reprogramming is required, it will be reprogrammed in the United States using the programming pads found on the backside of the PCB. The boards are reprogrammed on a reprogramming dock for loading the new software. Other PCB's will be set to a default mode, but the user will have the ability to select more than 15 different function modes already found in the PCB program utilizing the switch found on the PCB to set the PCB into program mode. The program will be selected by the number of clicks the switch receives.

You report that you are currently able to sell a version of the LED blank assemblies with multiple functions which could be used as a flashlight, a novelty device, a signaling device, or a tactical light. The end user determines how they want to use the LED blank assembly. Buyers of this version will be made aware of their ability to switch between different program modes and how to do it. However, for the Sportsman Flashlight or the Special Ops Flashlight, the LED blank assemblies program selection will be entered prior to shipping, and there is no ability to change modes. The software may be upgraded, but the LED blank assemblies need to be returned to the company for reprogramming. Once the LED blank assembly is returned, it no longer has to be disassembled to reach the reprogramming pads. The switch may be manipulated to give the customer their desired change.

ISSUE:

What is the country of origin of the flashlights and the LED assemblies for government procurement purposes?

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 C.F.R § 177.21 et seq., which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 et seq.), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purpose of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B): An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R § 177.22(a) defining ''country of origin'' in identical terms

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of Subpart B of Part 177 consistent with the Federal Procurement Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Procurement Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1).

The Federal Procurement Regulations define ''U.S.-made end product'' as: * * * an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. *See* 48 C.F.R. § 25.003. Therefore, the question presented in this final determination is whether, as a result of the operations performed in the United States, the imported flashlight devices are substantially transformed into products of the United States.

A substantial transformation is said to have occurred when an article emerges from a manufacturing process with a name, character, or use that differs from the original material subjected to the process. *M.B.I. Merchandise Industries, Inc.* v. *United States,* 16 C.I.T. 495, 502 (1992) (citing *United States* v. *Gibson-Thomsen Co.,* C.C.P.A. 267, 270 (C.A.D. 98) (1940)) The question of whether a substantial transformation occurs for marking purposes is a question of fact; to be determined on a case-by-case basis. *National Hand Tool Corp.* v. *United States,* 16 C.I.T. 308, 311 (1992) (quoting *Uniroyal Inc. United States,* 3 C.I.T. 220, 542 F. Supp. 1026 (1982), aff'd, 1 Fed.Cir. 21, 702 F.2d 1022 (1983)).

Assembly operations which are minimal or simple, as opposed to complex or meaningful will generally not result in a substantial transformation. In determining whether the United States processing constitutes a substantial transformation, the issue is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article. *Belcrest Linens* v. *United States,* 573 F. Supp.1149 (CIT 1983), aff'd, 741 F.2d 1368 (Fed. Cir. 1984). *See also* C.S.D. 85–25. If the manufacturing or combining process is merely a minor one which leaves the identity of the imported article intact, a substantial transformation has not occurred. *See Uniroyal.*

CBP considers the totality of the circumstances in determining whether an imported article loses it identity when it is combined with other articles in the United States. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. CBP takes into account such factors as resources expended on product design and development, the extent and nature of post-assembly inspection and testing procedures, and degree of worker skill required during the actual manufacturing process. *See* HQ H107335 dated September 9, 2010; and HQ H006417 dated August 20, 2008. No single factor is determinative.

We conclude that the LED blank assemblies provide the essential character to the finished Special Ops and Sportsman flashlights. The LED blank assemblies are clearly the dominant component contained in the flashlights. When they are imported into the United States, the LEDs blank assemblies which are produced in India, incorporate the four light emitting diodes and a push–button switch that control the LEDs. Thus, they are capable of generating the four different light colors that are the defining characteristic of the flashlights. As such, they possess all the basic functions of the two finished flashlights. In our judgment, the assembly of the other components with LED blank assemblies to make the finished flashlights constitutes a simple assembly operation that involves a small number of components which does not appear to require a considerable amount of time, a high degree of skill or attention to detail. Although the LEDs require programming to allow them to function as flashlights rather than in some other capacity such as signaling, decorative or novelty devices, the programming operation is not sufficiently complex to change the identity or nature of the devices. After the software is loaded onto the LED blank assemblies, the devices still function to emit light. Therefore, we conclude that the LED blank assemblies imported from India are not substantially transformed as a result of the processing operations performed in the United States to make the two versions of the finished flashlights. Consequently, the country of the origin of the finished Special Ops and the Sportsman Flashlights for government procurement purposes is the same as the country of origin of the imported LED blank assemblies, namely India.

HOLDING:

The country of origin of the Special Ops Flashlight, Sportsman Flashlight and Light-Emitting Diodes (LED) blank assemblies for government procurement purposes is India.

Sincerely,

Sandra L. Bell, Executive Director
Regulations and Rulings Office of International Trade

[FR Doc. 2012–11345 Filed 5–10–12; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5607–N–15]

Mortgagee's Certificate of Fees and Escrow and Surety Bond Against Defects Due to Defective Material and/or Faulty Workmanship

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* July 10, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, Room 9120 or the number for the Federal Relay Information Service, 1–800–877–8330.

FOR FURTHER INFORMATION CONTACT: Daniel J. Sullivan, Acting Director, Office of Multifamily Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 402–6130 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Mortgagee's Certificate of Fees and Escrow and Surety Bond Against Defects Due to Defective Material and/or Faulty Workmanship.

OMB Control Number, if applicable: 2502–0468.

Description of the need for the information and proposed use: The information collection is used by Mortgagees to ensure that fees are within acceptable limits and the required escrows will be collected. HUD determines the reasonableness of the fees and uses the information in calculating the financial requirement for closing.

Agency form numbers, if applicable: HUD–2434 and HUD–3259.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of burden hours is 1050. The number of respondents is 1,000. The number of annual responses is 2,000; the frequency of each response is once for each application submitted for mortgage insurance.

Status of the proposed information collection: This is an extension of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., chapter 35, as amended.

Dated: *May 7, 2012.*

Ronald Y. Spraker,

Acting General Deputy Assistant Secretary for Housing—Acting General Deputy Federal Housing, Commissioner.

[FR Doc. 2012–11517 Filed 5–10–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5601–N–18]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For

complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: ARMY: Ms. Veronica Rines, Department of the Army, Office of the Assistant Chief of Staff for Installation Management, DAIM–ZS, Room 8536, 2511 Jefferson Davis Hwy, Arlington, VA 22202; GSA: Mr. John E.B. Smith, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405; INTERIOR: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 1801 Pennsylvania Ave. NW., 4th Floor, Washington, DC 20006: (202) 208–5399; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426 (202) 501–0084; (These are not toll-free numbers).

Dated: May 3, 2012.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

Title V, Federal Surplus Property Program Federal Register Report for 05/11/2012

Suitable/Available Properties

Building

Alabama

Federal Bldg. & Courthouse
1118 Greensboro Ave.
Tuscaloosa AL 35401
Landholding Agency: GSA
Property Number: 54201220005
Status: Surplus
GSA Number: AL–0074–ZZ
Comments: 10,494 sf.; federal offices/courthouse; roof needs extensive repairs; severe leaks around drains; asbestos identified

Hawaii

5 Bldgs.
Marine Corps Base
Kaneohe HI 96863
Landholding Agency: Navy
Property Number: 77201220005
Status: Excess
Directions: 98, 3090, 3091, 3093, 4091
Comments: off-site removal only; relocation may be difficult due to deteriorated conditions; sf. varies; usage varies; needs extensive repairs

Kentucky

5 Bldgs.
Blue Grass Army Depot
Richmond KY 40475
Landholding Agency: Army
Property Number: 21201220045
Status: Underutilized
Directions: 501, 558, 909, 1003, 1500
Comments: off-site removal only; relocation may be difficult due to extremely poor conditions; sf varies; current use storage; contact Army for further details

27 Bldgs
Blue Grass Army Depot
Richmond KY 40475
Landholding Agency: Army
Property Number: 21201220046
Status: Underutilized
Directions: F0446–0469, G0470–0474, G0476–0479, H0483–0489, J0491–0493, J0495–0498
Comments: off-site removal only; 168 sf. for each; safety shelter; relocation may be difficult due to poor conditions

E0450–0457 & E0459
Blue Grass Army Depot
Richmond KY 40475
Landholding Agency: Army
Property Number: 21201220047
Status: Underutilized
Comments: off-site removal only; 168 sf. for each; safety shelter; relocation may be difficult due to poor conditions

D0440–D0449
Blue Grass Army Depot
Richmond, KY 40475
Landholding Agency: Army
Property Number: 21201220048
Status: Underutilized
Comments: off-site removal only; 168 sf. for each; safety shelter; relocation may be difficult due to poor conditions

C0431–C0438
Blue Grass Army Depot
Richmond KY 40475
Landholding Agency: Army
Property Number: 21201220049
Status: Underutilized
Comments: off-site removal only; 168 sf. for each; safety shelter; relocation may be difficult due to poor conditions

B0420–B0429
Blue Grass Army Depot
Richmond KY 40475
Landholding Agency: Army
Property Number: 21201220050
Status: Underutilized
Comments: off-site removal only; 168 sf. for each; safety shelter; relocation may be difficult due to poor conditions

A0410–0419
Blue Grass Army Depot
Richmond KY 40475
Landholding Agency: Army
Property Number: 21201220051
Status: Underutilized
Comments: Off-site removal only; 168 sf. each; safety shelter; relocation may be difficult due to conditions of properties

Maryland

Consumer Products Safety Commission
10901 Darnestown Rd.
Gaithersburg MD 20878
Landholding Agency: GSA
Property Number: 54201220004
Status: Surplus.
GSA Number: NCR–G–MR–1107–01
Directions: property includes building and land
Comments: 37,543 sf.; office/warehouse space; secured area; however, will not interfere w/conveyance; contact GSA for further details

Michigan

Nat'l Weather Svc Ofc
214 West 14th Ave.
Sault Ste. Marie MI
Landholding Agency: GSA
Property Number: 54200120010
Status: Excess
GSA Number: 1–C–MI–802
Comments: Previously unavailable; however, the property is 'available' as a facility to assist the homeless; 2230 sq. ft., presence of asbestos, most recent use—office

Oregon

Rager Ranger Station House
7615 Rager Rd.
Paulina OR 97751
Landholding Agency: GSA
Property Number: 54201220003
Status: Excess
GSA Number: 9–A–OR–0798
Comments: Off-site removal only; 1,560 sf.; residential; extensive rehabilitation needed; contact GSA for further details

Land

Colorado

.07 Acres
Bureau of Reclamation
Dolores CO

Landholding Agency: Interior
Property Number: 61201220006
Status: Excess
Comments: Narrow strip of land; construction or structures are prohibited; assemblage to an adjoining parcel; as standalone parcel does not conform to county regs. for residential or commercial use

[FR Doc. 2012–11091 Filed 5–10–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–R–2012–N080; FXRS12650400000S3–123–FF04R02000]

Chassahowitzka National Wildlife Refuge, FL; Draft Comprehensive Conservation Plan and Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), announce the availability of a draft comprehensive conservation plan and environmental assessment (Draft CCP/EA) for Chassahowitzka National Wildlife Refuge (NWR) in Citrus and Hernando Counties, Florida, for public review and comment. In this Draft CCP/EA, we describe the alternative we propose to use to manage this refuge for the 15 years following approval of the final CCP.

DATES: To ensure consideration, we must receive your written comments by June 11, 2012.

ADDRESSES: You may obtain a copy of the Draft CCP/EA by contacting Mr. Michael Lusk via U.S. mail at Chassahowitzka National Wildlife Refuge, 1502 SE. Kings Bay Drive, Crystal River, Florida 34429. Alternatively, you may download the document from our Internet Site at *http://southeast.fws.gov/planning* under ''Draft Documents.'' Comments on the Draft CCP/EA may be submitted to the above postal address or by email to: *ChassCCP@fws.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Morris at 850/567–6202 (telephone); or via email at: *ChassCCP@fws.gov*.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we continue the CCP process for Chassahowitzka NWR started through a notice in the **Federal Register** on June 8, 2009 (74 FR 27173). For more about the refuge and our CCP process, please see that notice.

Located about 60 miles north of Tampa, the 30,843-acre Chassahowitzka NWR was established by authority of the Migratory Bird Conservation Act on June 15, 1943, as ''an inviolate sanctuary'' for wintering waterfowl and other migratory birds. In 1976, Congress designated roughly three-quarters of the refuge (23,579 acres) as wilderness under the Wilderness Act of 1964 (16 U.S.C. 1131–1136).

The refuge's diverse ecosystems, including prime, estuarine habitat, hosts a myriad and abundance of flora and fauna. The marshlands, swamplands, shallow bays, and tidal streams provide both the quantity and quality of aquatic plant and animal life required to support thousands of wintering waterfowl, marsh and waterbirds, shorebirds, fishes, and a variety of animal species that depend on a marine environment. The refuge also has 2,560 acres of hardwood swamplands and 250 acres of upland forest. Notable imperiled species include Florida manatees and an experimental population of whooping cranes introduced to the marsh habitats over a decade ago by means of a partnership.

Background

The CCP Process

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Administration Act.

Priority resource issues addressed in the Draft CCP/EA include: (1) Priority imperiled species (e.g., manatees and whooping crane); (2) determining the habitat needs of migratory birds and the cause of waterfowl population declines on the refuge since the 1970s; (3) evaluating the external threats of potential loss of water quality and quantity; (4) controlling invasive plant and pest animal species; (5) documenting climate change effects on refuge resources (6) protecting natural, cultural and wilderness resources; (7) limited accessibility issues; (8) administrative resources; and (9) partnerships.

CCP Alternatives, Including Our Proposed Alternative

We developed three alternatives for managing the refuge (Alternatives A, B, and C), with Alternative C as our proposed alternative. A full description of each alternative is in the Draft CCP/EA. We summarize each alternative below.

Alternative A: Current Management (No Action)

This refuge is closer to pristine and has much less public use than most areas of Florida, so the goal under all three alternatives is to maintain its resources. To date, this has been done with minimal management by a small staff. Under this alternative, ongoing programs would continue. Species of Federal responsibility, such as threatened and endangered species and migratory birds, would continue to be monitored at present levels. High-profile, imperiled species, such as manatees and whooping cranes, would remain the focus. Additional species monitoring would occur as opportunistic events when contacts outside our staff offer support. Current habitat management, including prescribed fire, would continue (to improve crane habitat and to address fuel loads in uplands). Management of exotic, invasive, and nuisance animal and plant species would continue to be opportunistic. The public use programs of hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation and other existing uses would continue at present levels. Acquisition of inholding lands into the refuge would occur as willing sellers and funding become available. There is no staff dedicated exclusively to this refuge; instead, refuge staff draws from the staff assigned to the Crystal River NWR Complex (Complex), which also includes the Tampa Bay Refuges. This includes mostly the manager, deputy manager, wildlife biologist, and three park rangers (i.e., two wildlife officers and one visitor services staff). Alternative A presents the baseline upon which the other two alternatives

are expanded, but with differing management approaches.

Alternative B: Increased Research and Management via Partnerships

Alternative B proposes increased research and management capability, primarily through the use of cooperative partnerships and outside funding, with a modest increase of staff (three positions for the Complex). Research would be enhanced beyond priority, high-profile imperiled species. Because much baseline data are needed beyond the current surveying and monitoring protocols, this alternative would seek to initiate studies of a broader suite of species and to document noted declines of refuge habitat and species (waterfowl) and climate-change impacts. Since the refuge is accessible mostly by water from off-site, non-Service-owned ramps, we would provide more complete information to help the public locate the refuge via water. Studies would be conducted to assess visitor and commercial use effects on refuge resources; further, in Citrus County, commercial uses would require a special use permit issued by the refuge. A volunteer coordinator position is proposed to expand the volunteer corps and programs and to train and use volunteers to promote interpretation, voluntary compliance with refuge regulations, and the new environmental education programs of the refuge.

Alternative C: Adaptive Management (Proposed Alternative)

Alternative C would also heavily rely on our extensive partnerships and promote some new ones. We would rely on and use a volunteer corps for every program area and investigate the use of prison crews for maintenance work. This alternative assumes Service funding above current levels for research studies and facilities development and proposes additional staffing (eight positions for the Complex), to provide optimal resource protection and management capability. Research would include a broader suite of species, as well as habitat studies to adaptively manage for wildlife populations. The impacts of commercial and visitor use and external threats to the refuge would be studied and the results of those studies applied to refuge management and public use. Upland uses would be promoted though the development of improved facilities and access, and an observation platform and kayak landing would be added to the Dog Island facility, accessed by boat. The addition of key positions, such as a law enforcement officer, a volunteer coordinator, and biological and computer-mapping technicians, would allow for greater resource study, mapping, data analysis, and enforcement. The hiring of a wildlife refuge specialist and office assistant would support staff and provide a dedicated outreach coordinator. Refuge facilities would be improved for both visitor services and personnel, including projects to replace the headquarters office (to reduce flooding potential) and build a pole barn and make other smaller improvements to the maintenance area and shop. For all alternatives, ''green'' options, materials, and energy efficiency would be included in the design and construction of new facilities and in equipment replacement.

Next Step

After the comment period ends, we will analyze the comments and address them.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment–including your personal identifying information–may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd et seq.).

Dated: April 17, 2012.

Mark J. Musaus,

Acting Regional Director.

[FR Doc. 2012–11393 Filed 5–10–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Renewal of Agency Information Collection for Bureau of Indian Education Collection Activities; Request for Comments

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Affairs (BIA) is seeking comments on renewal of Office of Management and Budget (OMB) approval for the collection of information for the Tribal Colleges and Universities Application for Grants, authorized by OMB Control Number 1076–0018, and the Tribal Colleges and Universities Annual Report Form, authorized by OMB Control Number 1076–0105. Both of these information collections expire September 30, 2012.

DATES: Submit comments on or before July 10, 2012.

ADDRESSES: You may submit comments on the information collection to Juanita Keesing, U.S. Department of the Interior, Bureau of Indian Education, 1849 C Street NW., Washington, DC 20240; email: *Juanita.Keesing@bie.edu.*

FOR FURTHER INFORMATION CONTACT: Juanita Keesing, (202) 208–3559.

SUPPLEMENTARY INFORMATION:

I. Abstract

Each tribally-controlled college or university requesting financial assistance under the Tribally Controlled Colleges and Universities Assistance Act of 1978, as amended, 25 U.S.C. 1801 *et seq.* (Act) is required by 25 U.S.C. 1807(a) and 25 CFR 41.8 to provide information for the purpose of securing a grant. Similarly, each tribally-controlled college or university that receives financial assistance under the Act is required by 25 U.S.C. 1808(c)(1) and 25 CFR 41.9 to provide a report on the use of funds received.

II. Request for Comments

The BIA requests your comments on these collections concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents, such as through the use of automated collection techniques or other forms of information technology.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it has a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personally identifiable information, be

advised that your entire comment—including your personally identifiable information—may be made public at any time. While you may request that we withhold your personally identifiable information, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 1076–0018.

Title: Tribal Colleges and Universities Application for Grants Form.

Brief Description of Collection: Collection of the information is mandatory under the Tribally Controlled Colleges and Universities Assistance Act of 1978, as amended, 25 U.S.C. 1801 *et seq.,* for the respondent to receive or maintain a benefit.

Type of Review: Extension without change of a currently approved collection.

Respondents: Tribal college and university administrators.

Number of Respondents: 26 per year, on average.

Total Number of Responses: 26 per year, on average.

Frequency of Response: Annually.

Estimated Time per Response: 1 hour.

Estimated Total Annual Hour Burden: 26 hours.

* * * * *

OMB Control Number: 1076–0105.

Title: Tribal Colleges and Universities Annual Report Form.

Brief Description of Collection: Collection of the information is mandatory under the Tribally Controlled Colleges and Universities Assistance Act of 1978, as amended, 25 U.S.C. 1801 *et seq.,* for the respondent to receive or maintain a benefit, specifically an operating grant.

Type of Review: Extension without change of a currently approved collection.

Respondents: Tribal college and university administrators.

Number of Respondents: 26 per year, on average.

Frequency of Response: Annually.

Estimated Time per Response: 3 hours.

Estimated Total Annual Hour Burden: 78 hours.

Dated: May 4, 2012.

Alvin Foster,

Assistant Director for Information Resources.

[FR Doc. 2012–11436 Filed 5–10–12; 8:45 am]

BILLING CODE 4310–6W–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZ956000.L14200000.BJ0000.241A]

Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Survey; Arizona.

SUMMARY: The plats of survey of the described lands were officially filed in the Arizona State Office, Bureau of Land Management, Phoenix, Arizona, on dates indicated.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The plat (in 6 sheets) representing the dependent resurvey, subdivision of sections 25 & 33 and metes-and-bounds survey of the Wabayuma Peak Wilderness Boundary, Township 19 North, Range 16 West, accepted April 26, 2012, and officially filed May 1, 2012, for Group 983, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

A person or party who wishes to protest against any of these surveys must file a written protest with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

FOR FURTHER INFORMATION CONTACT: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona, 85004–4427. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Stephen K. Hansen,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 2012–11473 Filed 5–10–12; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZ956000.L14200000.BJ0000.241A]

Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Survey; Arizona.

SUMMARY: The plats of survey of the described lands were officially filed in the Arizona State Office, Bureau of Land Management, Phoenix, Arizona, on dates indicated.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The plat representing a dependent resurvey and metes-and-bounds surveys in the SW¼NE¼ and in the SE¼NW¼ of Section 26, Township 3 North, Range 5 East, accepted April 23, 2012, and officially filed April 25, 2012, for Group 1102, Arizona.

This plat was prepared at the request of the Bureau of Reclamation.

The plat representing a dependent resurvey, subdivision of section and metes-and-bounds surveys in Sections 25 and 36, Township 5 North, Range 2 East, accepted April 23, 2012, and officially filed April 25, 2012, for Group 1102, Arizona.

This plat was prepared at the request of the Bureau of Reclamation.

A person or party who wishes to protest against any of these surveys must file a written protest with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

FOR FURTHER INFORMATION CONTACT: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona, 85004–4427. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual.

You will receive a reply during normal business hours.

Stephen K. Hansen,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 2012–11408 Filed 5–10–12; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDB00100 LF1000000.HT0000 LXSS024D0000 4500034147]

Notice of Public Meeting: Resource Advisory Council to the Boise District, Bureau of Land Management, U.S. Department of the Interior

AGENCY: Bureau of Land Management, U.S. Department of the Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Boise District Resource Advisory Council (RAC), will hold a meeting as indicated below.

DATES: The meeting will be held June 14, 2012, at the Boise District Office, located at 3948 S. Development Avenue, Boise, Idaho, beginning at 9:00 a.m. and adjourning at 4:30 p.m. Members of the public are invited to attend. A public comment period will be held.

FOR FURTHER INFORMATION CONTACT: MJ Byrne, Public Affairs Officer and RAC Coordinator, BLM Boise District, 3948 Development Ave., Boise, ID 83705, Telephone (208) 384–3393.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in southwestern Idaho. Items on the agenda include a summary of the report with recommendations by the Idaho Governor's Sage-Grouse Conservation Task Force, and BLM's sage-grouse conservation efforts. An update on the Paradigm Project and the Comprehensive Plan of Conservation Measures Addressing the Threats of Fire and Exotic Annual Plants to Greater Sage-Grouse and its Habitat will be provided for discussion. Each field manager will discuss progress being made on priority actions in their offices. Agenda items and location may change due to changing circumstances. The public may present written or oral comments to members of the Council. At each full RAC meeting, time is provided in the agenda for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance should contact the BLM Coordinator as provided above. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Dated: May 4, 2012.

Meagan M. Conry,

Acting District Manager.

[FR Doc. 2012–11406 Filed 5–10–12; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZ910000.L12100000.XP0000LXSS150A 00006100.241A]

State of Arizona Resource Advisory Council Meetings

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM), Arizona Resource Advisory Council (RAC) will meet in Phoenix, Arizona, as indicated below.

DATES: The RAC Recreation and Communities Working Group will meet on July 31 from 1 p.m. until 5 p.m. The Business meeting will be held on August 1 from 8 a.m. until 1 p.m.

ADDRESSES: The meetings will be held at the BLM National Training Center located at 9828 North 31st Avenue, Phoenix, Arizona 85051.

FOR FURTHER INFORMATION CONTACT: Deborah Stevens, Acting DSD for Communications, the Bureau of Land Management, Arizona State Office, One North Central Avenue, Suite 800, Phoenix, Arizona 85004–4427, 602–417–9504. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in Arizona. Planned agenda items include: A welcome and introduction of Council members; BLM State Director's update on BLM programs and issues; report by the RAC Recreation and Communities Working Group; RAC recommendations on the National Landscape Conservation System Strategy; RAC questions on District Managers' Reports; and other items of interest to the RAC. Members of the public are welcome to attend the Working Group and Business meetings. A public comment period is scheduled on the day of the Business meeting from 11:30 a.m. to noon for any interested members of the public who wish to address the Council on BLM or Forest Service recreation fee programs and business. Depending on the number of persons wishing to speak and time available, the time for individual comments may be limited. Written comments may also be submitted during the meeting for the RAC's consideration. Final meeting agendas will be available two weeks prior to the meetings and posted on the BLM Web site at: *http://www.blm.gov/az/st/en/res/rac.html*. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the RAC Coordinator listed above no later than two weeks before the start of the meeting. Under the Federal Lands Recreation Enhancement Act, the RAC has been designated as the Recreation Resource Advisory Council (RRAC) and has the authority to review all BLM and Forest Service recreation fee proposals in Arizona. The RRAC will not review any recreation fee proposals at this meeting.

Raymond Suazo,

State Director.

[FR Doc. 2012–11478 Filed 5–10–12; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–0512–10197; 2200–3200–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before April 21, 2012. Pursuant to section 60.13 of 36 CFR Part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by May 29, 2012. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

ALABAMA

Baldwin County

Foley Downtown Historic District (Boundary Decrease), Parts of Alston, McKenzie, N. & S. Laurel, & W. Orange Sts., Foley, 12000316

FLORIDA

St. Johns County

Father Francisco Lopez Statue, 27 Ocean Ave., Saint Augustine, 12000317

IOWA

Adams County

Corning Commercial Historic District, 513–824 Davis, & 701–829 Benton Aves., & cross streets, Corning, 12000318

WISCONSIN

Milwaukee County

Peckham Junior High School, 3245 N. 37th St., Milwaukee, 12000319

A request for removal has been made for the following resource:

CALIFORNIA

San Diego

Aztec Bowl—Hardy Ave. between 55th St. and Campanile Dr., San Diego State University, San Diego, 94000402

[FR Doc. 2012–11460 Filed 5–10–12; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Statement of Recovery Forms

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of RUN FRFMWorkers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, ''Statement of Recovery Forms,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before June 11, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain*, on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The statement of recovery forms (Forms CA–1108 and CA–1122) are used to obtain information about amounts received as the result of final judgments in litigation, or a settlement of the litigation, brought against a third party who is liable for damages due to a Federal employee comprehensive work-related injury. A Federal employee can sustain a work-related injury, for which he or she is eligible for compensation under the Federal Employees' Compensation Act (FECA), under circumstances that create a legal liability for some third party to pay damages for the same injury. When this occurs, the FECA authorizes the Secretary of Labor either to require the employee to assign his or her right of action to the United States or to prosecute the action. *See* 5 U.S.C. 8131. When the employee receives a judgment or a settlement of the action, he or she must reimburse the United States for past compensation payments and if there is a surplus future compensation payments as the FECA provides that the employee must refund to the United States the amount of compensation paid by the United States and credit any surplus on future payments of compensation. *See* 5 U.S.C. 8132. The OWCP is revising this ICR by reformatting the forms. The changes are not expected to affect public burden.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under OMB Control Number 1240–0001. The current OMB approval is scheduled to expire on June 30, 2012; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. Any changes will only take effect after OMB approval. For additional information, see the related notice published in the **Federal Register** on February 9, 2012 (77 FR 6823).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should reference OMB Control Number 1240–

0001. The OMB is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Statement of Recovery Forms.

OMB Control Number: 1240–0001.

Affected Public: Individuals or Households, and Private Sector—Businesses or Other for Profits.

Total Estimated Number of Respondents: 2,832.

Total Estimated Number of Responses: 2,832.

Total Estimated Annual Burden Hours: 1,346.

Total Estimated Annual Other Costs Burden: $1,360.

Dated: May 7, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–11376 Filed 5–10–12; 8:45 a.m.]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Employment and Training Administration

Request for Certification of Compliance—Rural Industrialization Loan and Grant Program

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Employment and Training Administration is issuing this notice to announce the receipt of a ''Certification of Non-Relocation and Market and Capacity Information Report'' (Form 4279–2) for the following:

Applicant/Location: Samoa Cold Storage, Inc.

Principal Product/Purpose: The loan, guarantee, or grant application will establish a new cold storage facility, which included the demolition of the interior of the existing facility, renovations and improvements, repairs and upgrades and the purchase and installation of refrigeration and related machinery and equipment at a plant located in the Village of Anua, Ma'oputasi County, American Samoa. The NAICS industry code for this enterprise is: 493120 (cold storage warehousing services).

DATES: All interested parties may submit comments in writing no later than May 25, 2012. Copies of adverse comments received will be forwarded to the applicant noted above.

ADDRESSES: Address all comments concerning this notice to Anthony D. Dais, U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue, NW., Room S–4231, Washington, DC 20210; or email *Dais.Anthony@dol.gov;* or transmit via fax (202) 693–3015 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Anthony D. Dais, at telephone number (202)693–2784 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 188 of the Consolidated Farm and Rural Development Act of 1972, as established under 29 CFR part 75, authorizes the United States Department of Agriculture to make or guarantee loans or grants to finance industrial and business activities in rural areas. The Secretary of Labor must review the application for financial assistance for the purpose of certifying to the Secretary of Agriculture that the assistance is not calculated, or likely, to result in: (a) A transfer of any employment or business activity from one area to another by the loan applicant's business operation; or, (b) An increase in the production of goods, materials, services, or facilities in an area where there is not sufficient demand to employ the efficient capacity of existing competitive enterprises unless the financial assistance will not have an adverse impact on existing competitive enterprises in the area. The Employment and Training Administration within the Department of Labor is responsible for the review and certification process. Comments should address the two bases for certification and, if possible, provide data to assist in the analysis of these issues.

Signed at Washington, DC, this 4th day of May 2012.

Jane Oates,

Assistant Secretary for Employment and Training.

[FR Doc. 2012–11394 Filed 5–10–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Request for Certification of Compliance—Rural Industrialization Loan and Grant Program

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Employment and Training Administration is issuing this notice to announce the receipt of a ''Certification of Non-Relocation and Market and Capacity Information Report'' (Form 4279–2) for the following:

Applicant/Location: Samoa Tuna Processors, Inc.

Principal Product/Purpose: The loan, guarantee, or grant application will reopen a tuna cannery processing facility, which includes the demolition of the interior of the existing facility, comprehensive renovations and improvements, replace machinery and equipment and utilities repairs and other upgrades. The plant will be located in Village of Anua, Ma'oputasi County, American Samoa. The NAICS industry code for this enterprise is: 311711 (seafood canning).

DATES: All interested parties may submit comments in writing no later than May 25, 2012. Copies of adverse comments received will be forwarded to the applicant noted above.

ADDRESSES: Address all comments concerning this notice to Anthony D. Dais, U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW., Room S–4231, Washington, DC 20210; or email Dais.Anthony@dol.gov; or transmit via fax (202)693–3015 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Anthony D. Dais, at telephone number (202)693–2784 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 188 of the Consolidated Farm and Rural Development Act of 1972, as established under 29 CFR part 75, authorizes the United States Department of Agriculture to make or guarantee loans or grants to

finance industrial and business activities in rural areas. The Secretary of Labor must review the application for financial assistance for the purpose of certifying to the Secretary of Agriculture that the assistance is not calculated, or likely, to result in: (a) A transfer of any employment or business activity from one area to another by the loan applicant's business operation; or, (b) An increase in the production of goods, materials, services, or facilities in an area where there is not sufficient demand to employ the efficient capacity of existing competitive enterprises unless the financial assistance will not have an adverse impact on existing competitive enterprises in the area. The Employment and Training Administration within the Department of Labor is responsible for the review and certification process. Comments should address the two bases for certification and, if possible, provide data to assist in the analysis of these issues.

Signed at Washington, DC, this 4th day of May 2012.

Jane Oates,

Assistant Secretary for Employment and Training.

[FR Doc. 2012–11396 Filed 5–10–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Request for Certification of Compliance—Rural Industrialization Loan and Grant Program

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Employment and Training Administration is issuing this notice to announce the receipt of a ''Certification of Non-Relocation and Market and Capacity Information Report'' (Form 4279–2) for the following:

Applicant/Location: Tri Marine Samoa, Inc.

Principal Product/Purpose: The loan, guarantee, or grant application will establish a new fresh and frozen fish processing facility, which includes building renovations and improvements, repairs and upgrades, construction of a processing and storage area and the purchase and installation of refrigeration equipment at a plant located in the Village of Anua, Ma'oputasi County, American Samoa. The NAICS industry code for this enterprise is: 311712 (fresh and frozen seafood processing).

DATES: All interested parties may submit comments in writing no later than May 25, 2012. Copies of adverse comments received will be forwarded to the applicant noted above.

ADDRESSES: Address all comments concerning this notice to Anthony D. Dais, U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW., Room S–4231, Washington, DC 20210; or email *Dais.Anthony@dol.gov;* or transmit via fax (202) 693–3015 (this is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Anthony D. Dais, at telephone number (202) 693–2784 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 188 of the Consolidated Farm and Rural Development Act of 1972, as established under 29 CFR Part 75, authorizes the United States Department of Agriculture to make or guarantee loans or grants to finance industrial and business activities in rural areas. The Secretary of Labor must review the application for financial assistance for the purpose of certifying to the Secretary of Agriculture that the assistance is not calculated, or likely, to result in: (a) A transfer of any employment or business activity from one area to another by the loan applicant's business operation; or, (b) An increase in the production of goods, materials, services, or facilities in an area where there is not sufficient demand to employ the efficient capacity of existing competitive enterprises unless the financial assistance will not have an adverse impact on existing competitive enterprises in the area. The Employment and Training Administration within the Department of Labor is responsible for the review and certification process. Comments should address the two bases for certification and, if possible, provide data to assist in the analysis of these issues.

Signed at Washington, DC, this 4th of May 2012.

Jane Oates,

Assistant Secretary for Employment and Training.

[FR Doc. 2012–11395 Filed 5–10–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed reinstatement of the ''BLS GREEN TECHNOLOGIES AND PRACTICES SURVEY.'' A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before July 10, 2012.

ADDRESSES: Send comments to Carol Rowan, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Carol Rowan, BLS Clearance Officer, at 202–691–7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The Occupational Employment Statistics (OES) program has been funded to collect and produce objective and reliable information on occupational employment and wages for green jobs at the establishment level. This is to be conducted through a special employer survey. This work is necessary to meet the publication objective outlined in the FY2012 Congressional Appropriation.

The Bureau of Labor Statistics (BLS) presented its approach to measuring

green jobs and published its final definition of green jobs in the September 21, 2010, **Federal Register** (75 FR 57506). The measurement approach includes two surveys: One on jobs related to producing green goods and services, and one on jobs related to using environmentally friendly production processes and practices.

The latter approach will be accomplished through a special employer survey. This information collection request is for the Green Technologies and Practices (GTP) Survey. This survey includes collecting the current employment for the establishment; collecting information on the use of environmentally friendly production processes within the establishment; and collecting the number, occupation, and wages paid to employees of the establishment performing environmentally friendly activities.

II. Current Action

Office of Management and Budget clearance is being sought for a reinstatement of the ''BLS Green Technologies and Practices Survey.'' The goal of BLS and its OES program is to produce economic statistics on employment related to the use of environmentally friendly technologies and practices across the U.S. economy. Using its business establishment register, the OES program intends to survey establishments about these green activities and the associated employment. The survey will identify employers performing green activities, determine whether they have any employees performing tasks associated with these activities, gather information to classify those employees according to the Standard Occupational Classification (SOC) system, and collect wage rate information.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Type of Review: Reinstatement.

Agency: Bureau of Labor Statistics.

Title: BLS Green Technologies and Practices Survey.

OMB Number: 1220–0184.

Affected Public: Private sector businesses or other for-profits and not-for-profit institutions; small businesses or organizations; Federal, State, and local governments.

Total Respondents: 26,251.

Frequency: One time.

Total Responses: 26,251.

Average Time per Response: 30 minutes.

Estimated Total Burden Hours:

GTP: FISCAL YEAR 2012

	Responses	Average response time (minutes)	Total response time (hours)
Private sector establishments	22,103	30	11,052
Local government establishments	2,738	30	1,369
State government establishments	870	30	435
Federal government establishments	540	30	270
Total	26,251	.....	13,126

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 4th day of May 2012.

Kimberley Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2012–11348 Filed 5–10–12; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed extension of the ''International Price Program—U.S. Import and Export Product Information.'' A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the Addresses section of this notice.

DATES: Written comments must be submitted to the office listed in the Addresses section of this notice on or before July 10, 2012.

ADDRESSES: Send comments to Nora Kincaid, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue NE., Washington, DC 20212. Written

comments also may be transmitted by fax to 202–691–5111 (this is not a toll free number).

FOR FURTHER INFORMATION CONTACT: Nora Kincaid, BLS Clearance Officer, 202–691–7628 (this is not a toll free number). (See Addresses section.)

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Import and Export Price Indexes, produced by the Bureau of Labor Statistics' International Price Program (IPP), measure price change over time for all categories of imported and exported products, as well as selected services. The IPP has produced the U.S. Import Price Indexes continuously since 1973 and the U.S. Export Price Indexes continuously since 1971. The Office of Management and Budget has listed the Import and Export Price Indexes as a Principal Federal Economic Indicator since 1982. The indexes are widely used in both the public and private sectors. The primary public sector use is the deflation of the U.S. monthly Trade Statistics and the quarterly estimates of U.S. Gross Domestic Product; the indexes also are used in formulating U.S. trade policy and in trade negotiations with other countries. In the private sector, uses of the Import Price Indexes include market analysis, inflation forecasting, contract escalation, and replacement cost accounting.

The IPP indexes are closely followed statistics, and are viewed as a sensitive indicator of the economic environment. The U.S. Department of Commerce uses the monthly statistics to produce monthly and quarterly estimates of inflation-adjusted trade flows. Without continuation of data collection, it would be extremely difficult to construct accurate estimates of the U.S. Gross Domestic Product. In addition, Federal policymakers in the Department of Treasury, the Council of Economic Advisers, and the Federal Reserve Board utilize these statistics on a regular basis to improve these agencies' formulation and evaluation of monetary and fiscal policy and evaluation of the general business environment.

II. Current Action

Office of Management and Budget clearance is being sought for the U.S. Import and Export Price Indexes. The IPP continues to modernize data collection and processing to permit more timely release of its indexes, and to reduce reporter burden. The IPP has expanded the use of its web application, introduced in 2003 to allow respondents to update their data online and more rapidly than using a paper-based form. Through February 2012, 82 percent of IPP respondents were providing prices via the web application or had agreed to start using this repricing method. Field Economists currently offer web repricing to all new respondents and at initiation, it is the preferred method of collection offered to companies.

IPP has also implemented a better screening process for identifying out-of-scope trade, resulting in fewer out-of-scope shipments identified during the initiation process.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Type of Review: Extension without change of a currently approved collection.

Agency: Bureau of Labor Statistics.

Title: International Price Program (IPP) U.S. Import and Export Price Indexes.

OMB Number: 1220–0025.

Affected Public: Private Sector, Business or other for-profits.

Form	Total respondents	Frequency	Total responses	Average time per response (hours)	Estimated total burden (hours)
Form 3008		Annually			
Imports	1800		1800	1.0	1800
Exports	1200		1200	1.0	1200
Total	3000		3000		3,000
Form 3007D		Monthly			
Imports	3300	[1] 8.2	27060	[2] .4106	11111
Exports	2200	[1] 8.0	17600	[3] .3771	6637
Total	5500		44660		17748
Totals			47660		20748

[1] During initiation, the respondent determines how many months he/she will need to supply data in a given year based upon how often the company changes its pricing information. The average company is requested to supply information 8.0 months per year for exports and 8.2 months per year for imports.

[2] Time to reprice is based upon 5 minutes of response time per item × 4.927 items = 24.635 minutes/60 = .4106 hours.

[3] Time to reprice is based upon 5 minutes of response time per item × 4.525 items = 22.625 minutes/60 = .3771 hours.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC this 7th day of May 2012.

Kimberley D. Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2012–11400 Filed 5–10–12; 8:45 am]

BILLING CODE 4510–24–P

LEGAL SERVICES CORPORATION

Request for Comments—LSC Budget Request for FY 2014

AGENCY: Legal Services Corporation.

ACTION: Request for Comments—LSC Budget Request for FY 2014.

SUMMARY: The Legal Services Corporation is beginning the process of developing its FY 2014 budget request to Congress and is soliciting suggestions as to what the request should be.

DATES: Written comments will be accepted until 12 noon, Eastern Daylight Time, on June 7, 2012.

ADDRESSES: Written comments may be submitted by mail, fax or email to David L. Richardson, Treasurer, Legal Services Corporation, 3333 K Street NW., Washington DC 20007; 202–295–1510 (phone); 202–337–6834 (fax); *david.richardson@lsc.gov.*

SUPPLEMENTARY INFORMATION: The mission of the Legal Services Corporation (''LSC'' or ''Corporation'') is to promote equal access to justice in our Nation and to provide for high-quality civil legal assistance to low-income persons. LSC submits an annual budget request directly to Congress and receives an annual direct appropriation to carry out its mission. For the current fiscal year, FY 2012, LSC received an appropriation of $348,000,000, of which $322,400,000 is for basic field programs and required independent audits; $4,200,000 is for the Office of Inspector General; $17,000,000 is for management and grants oversight; $3,400,000 is for technology initiative grants; and $1,000,000 is for loan repayment assistance. Public Law 112–55, 125 Stat. 629 (Nov. 18, 2011).

As part of its annual budget and appropriation process, LSC notifies the Office of Management and Budget (''OMB'') in September of each year as to what the LSC budget request to Congress will be for the next fiscal year. Accordingly, LSC is currently in the process of formulating its FY 2014 budget request. The Finance Committee of the LSC Board of Directors will meet on June 11, 2012, to hear testimony and commence deliberations on what to recommend to the full Board for adoption as the Corporation's FY 2014 budget request.

LSC invites public comment on what its FY 2014 budget request should be. Interested parties may submit comments to LSC by 12 noon, Eastern Daylight Time, on Thursday, June 7, 2012. More information about LSC may be found at *www.lsc.gov.*

Dated: May 7, 2012.

Victor M. Fortuno,

Vice President & General Counsel.

[FR Doc. 2012–11374 Filed 5–10–12; 8:45 am]

BILLING CODE 7050–01–P

LEGAL SERVICES CORPORATION

Notice of Proposed Revisions for the LSC Grant Assurances for Calendar Year 2013 Funding

AGENCY: Legal Services Corporation.

ACTION: Notice of proposed changes and request for comments.

SUMMARY: The Legal Services Corporation (''LSC'') intends to revise the LSC Grant Assurances for calendar year 2013 funding since the last publication of the LSC Grant Assurances for 2012 funding and is soliciting public comment on the proposed changes. The proposed revisions affect Grant Assurances 1, 5, 14(b), 14(c), 19(d), and 21. The revisions clarify existing grant assurances to make the provisions easier to understand. The proposed LSC grant assurances for calendar year 2013 funding, in redline format indicating the proposed changes to the current ''LSC 2012 Grant Assurances,'' are at *http://grants.lsc.gov/sites/default/files/Grants/ReferenceMaterials/2013-Grant-Assurances-Proposed.pdf.*

DATES: All comments and recommendations must be received on or before the close of business on June 11, 2012.

ADDRESSES: There are four options for sending comments to LSC: (1) Email comments to *LSCGrantAssurances@lsc.gov* (this is the preferred option); (2) post comments at *http://www.lsc.gov/contact-us;* (3) mail comments to: Legal Services Corporation, 3333 K Street NW., Third Floor, Washington, DC 20007, Attention: Reginald Haley; and (4) fax comments to 202.337.6813.

FOR FURTHER INFORMATION CONTACT: Reginald J. Haley; Office of Program Performance; Legal Services Corporation; at *haleyr@lsc.gov* or (202) 295–1545.

SUPPLEMENTARY INFORMATION: The purpose of the LSC grant assurances is to delineate the rights and responsibilities of LSC and the recipient pursuant to the provisions of the grant. As a grant making agency created by Congress, LSC has grant assurances that are intended to reiterate and/or clarify the responsibilities and obligations already applicable through existing law and regulations and/or obligate the recipient to comply with specific additional requirements in order to effectuate the purposes of the Legal Services Corporation Act, as amended, and other applicable law. A summary of the changes proposed follows.

Grant Assurance #1 notifies LSC recipients of applicable laws, rules, regulations, policies, guidelines, instructions, and other directives of LSC related to the grant. The proposed change to the grant assurance incorporates the full title of the LSC CSR Handbook.

Grant Assurance #5 informs LSC recipients of financial audit requirements and sanctions that may be imposed for failure to have an audit performed in accordance with LSC's Office of Inspector General audit guidance. The proposed change is the replacement of the word ''required'' with the word ''specified,'' to make the language more accurate.

Grant Assurance #14(b) requires LSC recipients to inform LSC of a change in the recipient's board chairperson. The proposed change specifies that LSC recipients must provide the name and contact information of the new board chairperson.

Grant Assurance #14(c) requires LSC recipients to inform LSC of a change in the recipient's chief executive officer (CEO). The proposed change specifies that LSC recipients must provide the name and contact information of the new CEO.

Grant Assurance #19(d) notifies LSC recipients of guidelines for planning the orderly conclusion of its role and responsibility as an LSC grantee. The proposed change updates the Web site address used to access the LSC guidelines.

Grant Assurance #21 notifies LSC recipients about the use of the LSC logo. The proposed change updates the Web site address used to access the LSC logo.

The proposed LSC grant assurances for calendar year 2013 funding, in redline format indicating the proposed

changes to the current ''LSC 2012 Grant Assurances,'' are at *http://grants.lsc.gov/sites/default/files/Grants/ReferenceMaterials/2013-Grant-Assurances-Proposed.pdf.* Interested parties are requested to provide comments concerning the proposed grant assurances for 2013 grant awards within a period of thirty (30) days from the date of publication of this notice.

Dated: May 8, 2012.

Janet LaBella,

Director, Office of Program Performance, Legal Services Corporation.

[FR Doc. 2012–11502 Filed 5–10–12; 8:45 am]

BILLING CODE 7050–01–P

MORRIS K. UDALL AND STEWART L. UDALL FOUNDATION, THE UNITED STATES INSTITUTE FOR ENVIRONMENTAL CONFLICT RESOLUTION

Agency Information Collection Activities; Renewal of Currently Approved Information Collection; Submission for OMB Review; Comment Request: U.S. Institute for Environmental Conflict Resolution Application for the National Roster of Environmental Conflict Resolution and Collaboration Professionals

AGENCY: Morris K. Udall and Stewart L. Udall Foundation, U.S. Institute for Environmental Conflict Resolution.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this document announces that the U.S. Institute for Environmental Conflict Resolution (the U.S. Institute), part of the Udall Foundation, will submit for Office of Management and Budget (OMB) review, a renewal request for the currently approved information collection (ICR), OMB control Number 3320–0008: Application for the National Roster of Environmental Conflict Resolution and Collaboration Professionals, currently operating pursuant to OMB clearance which expires August 31, 2012. The renewal request includes revisions to the currently approved collection.

The U.S. Institute published a **Federal Register** Notice on February 27, 2012 (Volume 77, Issue number 38, 11594, FR 2012–4445), to solicit public comments for a 60-day period. The U.S. Institute received one comment. The comment and the U.S. Institute's response are included in the ICR.

The purpose of this notice is to allow an additional 30 days for public comments regarding this information collection. Comments are invited on: (1) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information has practical utility; (2) the accuracy of the agency's estimate of the time spent completing the application (burden of the proposed collection of information); (3) ways to enhance the quality, utility, and clarity of the information collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of technology.

DATES: Comments must be submitted on or before June 11, 2012.

ADDRESSES: Direct comments to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Heidi King, 725 17th Street NW., Washington, DC 20503. Desk Officer for The Morris K. Udall and Stewart L. Udall Foundation, U.S. Institute for Environmental Conflict Resolution. *Heidi_R._King@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Patricia Orr, Director of Policy, Planning and Budget, U.S. Institute for Environmental Conflict Resolution, 130 South Scott Avenue, Tucson, Arizona 85701, Fax: 520–670–5530, Phone: 520–901–8548, Email: *orr@ecr.gov.*

SUPPLEMENTARY INFORMATION:

Abstract: The U.S. Institute is a non-partisan federal program established by Congress to provide impartial assistance to parties in resolving environmental, natural resource, and public lands conflicts involving the U.S. government. The U.S. Institute accomplishes much of its work by partnering, contracting with, or referral to, experienced practitioners. In addition, the U.S. Institute maintains the National Roster of Environmental Conflict Resolution and Collaboration Professionals (roster). The Application for the National Roster of Environmental Conflict Resolution and Collaboration Professionals (application) compiles data available from the resumes of environmental neutrals (mediators, facilitators, *etc.*) into a format that is standardized for efficient and fair eligibility review, database searches, and retrievals.

The roster, the application and the related entry criteria, were developed collaboratively and with the support of partner federal agencies including the Environmental Protection Agency. To apply for membership of the roster a professional needs to complete the application form one time. Once an application is approved, the roster member has access to update information online as needed.

The proposed collection is necessary for screening new applicants and the maintenance of the online roster system. The application is available from the U.S. Institute's Web site at *http://roster.ecr.gov/reference/documents/2012DRAFTRosterApplication.pdf.*

Burden Statement

Affected public: Environmental conflict resolution professionals (new respondents); existing roster members (for updating).

Frequency of Response—new applicants: One time for new applicants.

Frequency of Response—existing applicants: One time first year update by all existing roster members to update existing information to the new format, with suggested updating for major information changes in the following two years.

Estimated Average Annual Respondents: 195 (25 new respondents/year; 310 existing respondents in the first year, 100/year in the following two years).

Total Annual Hours Burden: 234.15 hrs (62.50 hours for new respondents; 465 hours for existing respondents in the first year to update their information to the new format, 25 hours per year for the following two years).

Annual Cost Burden: $11,055 new response and updates combined ($2,951 for new respondents/year; $21,953 for existing respondent updates in the first year, $1,180 for existing respondent updates in the following two years). Labor costs exclusively; no capital or start-up costs.

Authority: 20 U.S.C. 5601–5609.

Dated: May 7, 2012.

Ellen Wheeler,

Executive Director, Udall Foundation.

[FR Doc. 2012–11476 Filed 5–10–12; 8:45 am]

BILLING CODE 6820–FN–P

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Proposed Collection; Comments Request

April 30, 2012.

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Proposed Collection; Comments Request.

The National Endowment for the Arts (NEA) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork

Reduction Act of 1995 [Pub. L. 104–13, 44 U.S.C. Chapter 35] Copies of this ICR, with applicable supporting documentation, may be obtained by calling the National Endowment for the Arts' Director for Guidelines & Panel Operations, Jillian Miller, at 202/682–5004. Individuals who use a telecommunications device for the deaf (TTY/TDD) may call 202/682–5496 between 10 a.m. and 4 p.m. Eastern time, Monday through Friday.

Comments should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Endowment for the Arts, Office of Management and Budget, Room 10235, Washington, DC 20503 202/395–7316, within 30 days from the date of this publication in the **Federal Register**.

The Office of Management and Budget is particularly interested in comments which: Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used.

Enhance the quality, utility, and clarity of the information to be collected; and Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submissions of responses.

SUPPLEMENTARY INFORMATION:

Agency: National Endowment for the Arts.

Title: Panelist Profile Form.

Frequency: Every three years.

Affected Public: Individuals.

Estimated Number of Respondents: 250.

Total Burden Hours: 41.7.

Total Annualized Capital/Start Up Costs: 0.

Total Annual Costs (Operating/Maintaining systems or Purchasing Services): 0.

The National Endowment for the Arts' mission is to advance artistic excellence, creativity, and innovation for the benefit of individuals and communities.

With the advice of the National Council on the Arts and advisory panels, the Chairman establishes eligibility requirements and criteria for the review of applications for funding. Section 959 (c) of the Endowment's enabling legislation, as amended, directs the Chairman to utilize advisory panels to review applications and to make recommendations to the National Council on the Arts, which in turn makes recommendations to the Chairman.

The legislation requires the Chairman ''(1) to ensure that all panels are composed, to the extent practicable, of individuals reflecting a wide geographic, ethnic, and minority representation as well as to (2) ensure that all panels include representation of lay individuals who are knowledgeable about the arts * * *'' In addition, the membership of each panel must change substantially from year to year and each individual is ineligible to serve on a panel for more than 3 consecutive years. To assist with efforts to meet these legislated mandates regarding representation on advisory panels, the endowment has established an Automated Panel Bank System (APBS), a computer database of names, addresses, areas of expertise and other basic information on individuals who are qualified to serve as panelists for the Arts Endowment.

The Panelist Profile Form, for which clearance is requested, is used to gather basic information from qualified individuals recommended by the arts community; arts organizations; Members of Congress; the general public; local, state, and regional arts organizations; Endowment staff; and others.

Dated: May 7, 2012.

Kathleen Edwards,

Support Services Supervisor, National Endowment for the Arts.

[FR Doc. 2012–11320 Filed 5–10–12; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Arts Advisory Panel Meeting

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that fourteen meetings of the Arts Advisory Panel to the National Council on the Arts will be held at the Nancy Hanks Center, 1100 Pennsylvania Avenue NW., Washington, DC 20506 as follows (ending times are approximate):

Dance (application review): In room 716. This meeting will be closed.

Dates: May 31–June 1, 2012; 9:00 a.m. to 5:30 p.m. EDT on May 31st and 9:00 a.m. to 5:00 p.m. EDT on June 1st.

Artist Communities (application review): In room 714. This meeting will be closed.

Dates: June 4, 2012, from 9:00 a.m. to 4:45 p.m. EDT.

Local Arts Agencies (application review): In room 627. This meeting will be closed.

Dates: June 5, 2012 from 9:00 a.m.—2:00 p.m. EDT.

Dance (application review): In room 716. This meeting will be closed.

Dates: June 5–6, 2012; 9:00 a.m. to 5:30 p.m. EDT on June 5th and 9:00 a.m. to 5:00 p.m. EDT on June 6th.

Music (application review): In room 714. This meeting will be closed.

Dates: June 11–12, 2012. From 9:00 a.m. to 5:30 p.m. EDT on June 11th and 9:00 a.m. to 4:30 p.m. EDT on June 12th.

Presenting (application review): In room 627. This meeting will be closed.

Dates: June 11–12, 2012. From 9:00 a.m. to 5:30 p.m. EDT on June 11th and 9:00 a.m. to 3:00 p.m. EDT on June 12th.

Media Arts (application review): In room 730. This meeting will be closed.

Dates: June 12–13, 2012. From 9:00 a.m. to 5:30 p.m. EDT on June 12th and 9:00 a.m. to 5:00 p.m. EDT on June 13th.

Theater/Musical Theater (application review): In room 627. This meeting will be closed.

Dates: June 13–14, 2012. From 9:00 a.m. to 5:30 p.m. EDT on June 13th and 9:00 a.m. to 3:00 p.m. EDT on June 14th.

Arts Education (application review): In room 716. This meeting will be closed.

Dates: June 19, 2012, from 9:00 a.m. to 5:00 p.m. EDT.

Arts Education (application review): In room 716. This meeting will be closed.

Dates: June 20, 2012, from 9:00 a.m. to 5:00 p.m. EDT.

Folk and Traditional Arts (application review): In room 627. This meeting will be closed.

Dates: June 21, 2012 from 9:00 a.m. to 5:00 p.m. EDT.

Folk and Traditional Arts (application review): In room 627. This meeting will be closed.

Dates: June 22, 2012 from 9:00 a.m. to 4:00 p.m. EDT.

Opera (application review): In room 714. This meeting will be closed.

Dates: June 25, 2012 from 9:00 a.m. to 5:30 p.m. EDT.

Opera (application review): In room 714. This meeting will be closed.

Dates: June 26, 2012 from 9:00 a.m. to 5:30 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Further information with reference to

these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of Title 5, United States Code.

Dated: May 8, 2012.

Kathleen Edwards,

Support Services Supervisor, Administrative Services, National Endowment for the Arts.

[FR Doc. 2012–11431 Filed 5–10–12; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Chemistry; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Centers for Chemical Innovation (CCI) Solar Fuels: Powering the Planet Site Visit 2012, #1191.

Date and Time:

Tuesday, May 22, 2012 (7:00 p.m.–9:00 p.m.),
Wednesday, May 23, 2012 (7:00 a.m.–5:30 p.m.),
Thursday, May 24, 2012 (7:00 a.m.–1:00 p.m.).

Place: Hilton, Pasadena, California.

Type of Meeting: Partially-Open.

Contact Person: Zeev Rosenzweig, Program Director, Division of Chemistry, National Science Foundation, 4201 Wilson Blvd., Arlington, VA, 703–292–7719.

Purpose of Meeting: To provide advice and recommendations concerning center proposal submitted to NSF for financial support.

Agenda:

Tuesday, May 22, 2012

7:00 p.m.–9:00 p.m. Executive Session (Closed)

Wednesday, May 23, 2012

7:00 a.m. –8:15 a.m. Executive Session (Closed)
8:15 a.m.–12:10 p.m. Welcome & Session 1 (Center Overview) & Session 2 (Catalyst Research and Center Outreach) (Open)
12:10 p.m.–1:15 p.m. Executive Session (Closed)
1:15 p.m.–5:30 p.m. Poster Session & Session 3 (Integration Challenges) & Session 4 (Future Plans) (Open)

Thursday, May 24, 2012

7:00 a.m.–8:30 a.m. Executive Session (Closed)
8:30 a.m.–9:30 a.m. Meet with CCI Management and Steering Committees (Open)
9:30 a.m.–12:30 p.m. Report Writing (Closed)
12:30 p.m.–1:00 p.m. Executive Session (Closed)

Reason for Closing: The meeting is closed to the public because the Site Visitors will be reviewing proposal actions that will include privileged intellectual property and personal information that could harm individuals if they were disclosed. If discussions were open to the public, these matters that are exempt under 5 U.S.C. 552b(c)(4) and (6) of the Government Sunshine Act would be improperly disclosed.

Dated: May 8, 2012.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2012–11383 Filed 5–10–12; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–321 and 50–366; NRC–2012–0106]

Southern Nuclear Operating Company, Inc., Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Southern Nuclear Operating Company, Inc. (the licensee) to withdraw its December 15, 2011, application for proposed amendment to Facility Operating License Nos. DPR–57 and NPF–5 for the Edwin I. Hatch, Units 1 and 2, located in Appling County, Georgia.

The proposed amendment would have revised the Technical Specifications related to the plant service water (PSW) and ultimate heat sink surveillance requirements for the minimum water level in each PSW pump well of the intake structure.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on February 7, 2012 (77 FR 6148). However, by letter dated April 20, 2012, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated December 15, 2011, and the licensee's letter dated April 20, 2012, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available documents created or received at the NRC are accessible electronically through the Agencywide Documents Access and Management System (ADAMS) in the NRC's Library at *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by email to *pdr.resource@nrc.gov*.

Dated at Rockville, Maryland, this 3rd day of May 2012.

For the Nuclear Regulatory Commission.

Patrick G. Boyle,

Project Manager, Plant Licensing Branch II–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–11422 Filed 5–10–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–416; NRC–2012–0105]

Entergy Operations, Inc.; Grand Gulf Nuclear Station, Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft environmental assessment and finding of no significant impact, opportunity to comment.

DATES: Comments must be filed by June 11, 2012 Any potential party as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.4 who believes access to Sensitive Unclassified Non-Safeguards Information and/or Safeguards Information is necessary to respond to this notice must request document access by May 21, 2012.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and is publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2012–0105. You may submit comments by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0105. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov*.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of

Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

• *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2012–0105 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, by the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0105.

NRC's Agencywide Documents Access and Management System (ADAMS): You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* Documents may be viewed in ADAMS by performing a search on the document date and docket number. The Entergy Operations, Inc. (Entergy, the licensee), application for amendment is dated September 8, 2010, and supplemented by letters dated November 18, 2010, November 23, 2010, February 23, 2011 (four letters), March 9, 2011 (two letters), March 22, 2011, March 30, 2011, March 31, 2011, April 14, 2011, April 21, 2011, May 3, 2011, May 5, 2011, May 11, 2011, June 8, 2011, June 15, 2011, June 21, 2011, June 23, 2011, July 6, 2011, July 28, 2011, August 25, 2011, August 29, 2011, August 30, 2011, September 2, 2011, September 9, 2011, September 12, 2011, September 15, 2011, September 26, 2011, October 10, 2011 (two letters), October 24, 2011, November 14, 2011, November 25, 2011, November 28, 2011, December 19, 2011, February 6, 2012, February 15, 2012, February 20, 2012, March 13, 2012, March 21, 2012, April 5, and April 18, 2012 (two letters). Portions of the letters dated September 8 and November 23, 2010, and February 23, April 21, May 11, July 6, July 28, September 2, October 10, November 14, November 25, and November 28, 2011, and February 6, February 15, February 20, March 13, March 21, April 5, and April 18, 2012, contain sensitive unclassified non-safeguards information (proprietary) and, accordingly, have been withheld from public disclosure. The licensee's letters are publicly available in ADAMS at the accession numbers listed in the table below:

Document date	Accession No.
9/8/2010	ML120660409
11/18/2010	ML103260003
11/23/2010	ML103330093
2/23/2011	ML110540534
2/23/2011	ML110540540
2/23/2011	ML110540545
2/23/2011	ML110550318
3/9/2011	ML110680507
3/9/2011	ML110730025
3/22/2011	ML110820262
3/30/2011	ML110900275
3/31/2011	ML110900586
4/14/2011	ML111050134
4/21/2011	ML11112A098
5/3/2011	ML111240288
5/5/2011	ML111250552
5/11/2011	ML111320263
6/8/2011	ML111590836
6/15/2011	ML111670059
6/21/2011	ML111730235
6/23/2011	ML111750244
7/6/2011	ML111880138
7/28/2011	ML112101485
8/25/2011	ML112370770
8/29/2011	ML112410566
8/30/2011	ML112420169
9/2/2011	ML112490050
9/9/2011	ML112521284
9/12/2011	ML112550495
9/15/2011	ML112580223
9/26/2011	ML112690143
10/10/2011	ML112840155
10/10/2011	ML112840171
10/24/2011	ML112980113
11/14/2011	ML113190403
11/25/2011	ML113290137
11/28/2011	ML113320403
12/19/2011	ML113530656
2/6/2012	ML12039A071
2/15/2012	ML120470138
2/20/2012	ML12054A038
3/13/2012	ML120740083
3/21/2012	ML12082A025
4/5/2012	ML12097A055
4/18/2012	ML12109A308
4/18/2012	ML12109A290

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2012–0105 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS, and the NRC does not edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information in their comment submissions that they do not want to be publicly disclosed. Your request should state that the NRC will not edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

Federal Rulemaking Web Site: Public comments and supporting materials related to this notice can be found at *http://www.regulations.gov* by searching on Docket ID: NRC–2012–0105.

FOR FURTHER INFORMATION CONTACT: Alan B. Wang, Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1445; email: *AlanWang@nrc.gov.*

II. Introduction

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–29, issued to Entergy Operations, Inc. (Entergy, the licensee), for operation of the Grand Gulf Nuclear Station, Unit 1 (GGNS Unit 1), located in Claiborne County, in accordance with 10 CFR 50.90. In accordance with 10 CFR 51.21, the NRC has prepared this draft Environmental Assessment (EA) and draft Finding of No Significant Impact (FONSI) for the proposed action. The draft EA and draft FONSI are being published in the **Federal Register** with a 30-day public comment period ending June 11, 2012.

III. Environmental Assessment

Plant Site and Environs

The GGNS site is located in Claiborne County, Mississippi, on the east bank of the Mississippi River at River Mile (RM) 406, approximately 25 miles south of Vicksburg, Mississippi, and 37 miles north-northeast of Natchez, Mississippi.

The GGNS site consists of approximately 2,100 acres, comprised primarily of woodlands and former farms as well as two lakes, Hamilton Lake and Gin Lake. The land in the vicinity of GGNS is mostly rural. GGNS Unit 1 is a General Electric Mark 3 boiling-water reactor.

Identification of the Proposed Action

By application dated September 8, 2010, as supplemented, the licensee requested an amendment for an extended power uprate (EPU) for GGNS Unit 1 to increase the licensed thermal power level from 3,898 megawatts thermal (MWt) to 4,408 MWt, which represents an increase of approximately 13 percent above the current licensed thermal power and approximately 15 percent over the original licensed thermal power level of 3833 MWt. This change in core thermal power level requires the NRC to amend the facility's operating license. The operational goal of the proposed EPU is a corresponding increase in net electrical output of 178 megawatts electric (MWe). The proposed action is considered an EPU by the NRC because it exceeds the typical 7 percent power increase that can be accommodated with only minor plant changes. EPUs typically involve extensive modifications to the nuclear steam supply system.

The licensee plans to make several extensive physical modifications to systems necessary to generate and/or accommodate the increased feedwater and steam flow rates to achieve EPU power levels during a refueling outage currently scheduled for 2012. In addition, there will be land disturbance involving installation of a new radial well system. The actual power uprate, if approved by the NRC, would occur following the refueling outage in 2012.

The Need for the Proposed Action

The proposed action provides GGNS with the flexibility to increase its potential electrical output and to supply additional electrical generation to the State of Mississippi and the surrounding region.

Environmental Impacts of the Proposed Action

As part of the licensing process for GGNS Unit 1, the NRC published a Final Environmental Statement (FES) in 1981, *Final Environmental Statement for the Operation of the Grand Gulf Nuclear Station Units 1 and 2 (NUREG–0777).* The FES provides an evaluation of the environmental impacts associated with the construction and operation of GGNS Units 1 and 2 (Unit 2 has since been cancelled) over their licensed lifetimes. The NRC staff used information from the licensee's license amendment request and the FES to perform its EA for the proposed EPU.

There will be extensive changes made to the steam supply system of GGNS Unit 1 related to the EPU action, but no new construction is planned outside of existing facilities. No extensive changes are anticipated to existing buildings or plant systems that directly or indirectly interface with the environment. All necessary modifications would be performed in existing buildings at GGNS Unit 1 with the exception of the installation of a new radial well and additional cooling units being added to the auxiliary cooling tower. Modifications to the steam supply system of GGNS Unit 1 include the following: Replacing the reactor feed pump turbine rotors; replacing the main generator current transformers, replacing the high pressure turbine; replacing the moisture separator reheater shell and internals; replacing the steam dryer; and other modifications to upgrade the plant service water heat removal system.

The sections below describe the non-radiological and radiological impacts to the environment that may result from the proposed EPU.

Non-Radiological Impacts

Land Use and Aesthetic Impacts

Potential land use and aesthetic impacts from the proposed EPU include impacts from plant modifications at the GGNS site. The licensee states that any land disturbance activities, including those associated with EPU, are reviewed in accordance with Entergy procedures to ensure that necessary environmental protection measures are implemented during the project. They state that these measures would include provisions to protect such things as threatened and endangered species, cultural resources, wetland areas, water quality, etc.

The licensee's analysis concluded that additional cooling tower make-up water is projected to be needed (~3,200 gallons per minute (gpm)) due to the increase in heat load generated as a result of EPU, which also results in an increase in water loss through evaporation, blowdown, and drift. A new radial well is being installed to ensure sufficient cooling water is available to support the higher EPU power level because GGNS' existing radial wells have degraded over time and thus cannot perform at their design capacity. Activities to support the well construction include clearing and grubbing of trees, construction of a working pad using engineered fill, and excavation of trenches for supply piping to the plant service water header, discharge piping into the river, and electrical equipment feeders. The proposed working pad is designed to contain all the equipment needed for construction of the well and to provide an area for material laydown and parking. Activities conducted in wetland areas would be managed under a Section 404 permit issued by the United States Army Corps of Engineers (USACE). The remaining non-wetland areas would be managed under Mississippi Department of Environmental Quality (MDEQ) stormwater permitting program (Permit Number MSR15) and associated best management practices.

Improvements are also being made to the Heavy Haul Road, which connects the site to the barge slip area, to support activities associated with the installation of the new radial well and potential delivery of heavy equipment as discussed below. These improvements consist of refurbishing the existing road and road base in low areas or areas that have become washed out over the years. These refurbishment activities would occur within the plant site boundary with appropriate best management practices applied and in accordance with GGNS' National Pollutant Discharge Elimination System (NPDES) Permit MSR000883 and associated Stormwater Pollution Prevention Plan to control silt and erosion.

Entergy plans to use either the Port of Claiborne or the existing barge slip area on site for delivery of new transformers and other heavy equipment associated with the proposed EPU. In the event it is not feasible to use the Port of Claiborne, GGNS may conduct dredging activities in the existing barge slip area to accommodate delivery of such equipment. Activities associated with upgrading the barge slip would be managed under a Section 404 Permit issued by the USACE as previously discussed.

While some plant components would be modified, most changes related to the proposed EPU would occur within existing structures, buildings, and fenced equipment yards housing major components within the developed part of the site. Existing parking lots, road access, equipment lay-down areas, offices, workshops, warehouses, and restrooms would be used during plant modifications. Therefore, land use conditions would not change at the GGNS site. Also, there would be no land use changes along transmission line corridors, and no new transmission lines would be required.

Since land use conditions would not change at the GGNS site, and because any land disturbance would occur within previously disturbed areas, and those activities will be conducted in accordance with State and Federal permits to ensure the potential impacts are not significant, there would be little or no impact to aesthetic resources in the vicinity of GGNS Unit 1. Therefore, there would be no significant impact from EPU-related plant modifications on land use and aesthetic resources in the vicinity of the GGNS site.

Air Quality Impacts

Major air pollution emission sources at the GGNS site are regulated by the MDEQ in accordance with GGNS Air Permit 0420–00023. Nonradioactive emission sources at GGNS Unit 1 result primarily from periodic testing of diesel generators and fire water pump diesel engines, and operation of the cooling towers. There will be no changes to the emissions from these sources as a result of the EPU.

Some minor and short duration air quality impacts would occur during implementation of the EPU at the GGNS site. The main source of air emissions would come from the vehicles driven by outage workers needed to implement the EPU. However, this source will be short term and temporary. The majority of the EPU activities would be performed inside existing buildings and would not cause additional atmospheric emissions. Therefore, there would be no significant impact on air quality during and following implementation of the proposed EPU.

The licensee also evaluated the potential for an increase in particulate emissions that could occur as a result of the modification to the auxiliary cooling tower and the addition of two 60-gallon lube oil tanks associated with the new radial well pumps. These sources will result in some minor emissions of volatile organic compounds (VOC). The licensee plans to submit a modification to GGNS Air Permit 0420–00023 to the MDEQ for approval prior to these activities occurring to reflect the increase in particulate emissions.

Upon completion of the proposed EPU, non-radioactive air pollutant emissions would increase slightly due to the modification of the auxiliary cooling tower and the addition of two 60-gallon lube oil tanks for the new radial well pumps but will be regulated in accordance with the GGNS Air Permit with MDEQ. Therefore, there would be no significant impact on air quality in the region during and following implementation of the proposed EPU.

Water Use Impacts

Surface Water

The western boundary of the GGNS site is defined by the Mississippi River's eastern bank. At the site, the Mississippi River is about 0.5 miles wide at low flow and about 1.4 miles during a typical annual high flow period. The massive nature of the Mississippi River makes the liquid effluent discharges from the GGNS facility undetectable within the overall flow regime, and any changes in the quality are small and localized compared to the overall volume of water in the river. Hamilton and Gin are lakes on the GGNS site. These lakes are what remain of the former river channel after the Mississippi River moved to the west. Hamilton and Gin lakes are relatively small (Hamilton Lake is approximately 64 acres, and Gin Lake is approximately 55 acres) and shallow with an average depth of 8 to 10 feet. There is no effluent discharged or water drawn from these lakes for plant operations.

Limitations and monitoring requirements for plant effluent discharges are specified in the NPDES Permit. Discharges directly to the Mississippi River are required to be monitored continuously. Modifications of the nonradiological drain systems or other systems conveying wastewaters are not required for the EPU, and biocide/chemical discharges would be within existing permit limits. Although it is estimated that blowdown (the release of liquid effluent to clean the water in the system) would increase slightly (~825 gpm) based on evaporation, the EPU is not introducing any new contaminants or pollutants and is not increasing the amount of those potential contaminants presently allowed for release by GGNS Unit 1.

Chemical and biocide wastes are produced from processes used to control the pH in the coolant, to control scale, to control corrosion, and to clean and defoul the condenser. These waste liquids are typically combined with cooling water discharges in accordance with the site's NPDES Permit MS0029521. Sanitary wastewater from all plant locations are regulated by GGNS NPDES Permit MS0029521, and flow to an onsite sewage treatment plant prior to discharge into the Mississippi River. Solids associated with treatment of the sanitary wastewater are placed in drying beds and then managed appropriately for eventual offsite disposal.

Surface water and wastewater discharges are regulated by the MDEQ via the NPDES permit. The permits are reviewed by the MDEQ on a 5-year basis. The current GGNS NPDES permit, which has been administratively continued by the MDEQ based on Entergy's timely submittal of the permit renewal application, authorizes discharges from 11 outfalls into the Mississippi River. None of the NPDES permit limits would require a modification to support or implement the EPU.

Total surface water withdrawals in Claiborne County are predominantly for agricultural use (livestock and irrigation), with no surface water usage reported for public supply, domestic self-supplied systems, mining, hydroelectric power, thermoelectric power, or industrial or commercial uses.

The nearest downstream user of Mississippi River water is the Southeast Wood Fiber company located at the Claiborne County Port facility, 0.8 miles downstream of the GGNS site. The maximum intake requirement for this facility is less than 0.9 million gallons per day (mgd). There are only three public water supply systems in the State of Mississippi that use surface water as a source, and none of these are located within 50 miles of the GGNS site.

Based on the above, the NRC staff concludes that the proposed EPU will not have a significant impact on surface water in the area of GGNS, and operation under EPU conditions would not cause a water use conflict with other surface water users in the GGNS area.

Groundwater

There are 16 groundwater wells currently used for withdrawal purposes at the GGNS site. Groundwater is used for domestic water, once-through cooling for plant air conditioners, and for regenerating the water softeners at the Energy Services Center.

There are currently four radial wells which supply water to the plant service water system. Since additional cooling tower make-up water is projected to be needed (~3,200 gpm) due to the increase in heat load generated as a result of the EPU, and an increase in water loss through evaporation, blowdown, and drift, a new radial well is being installed to provide additional water needed during EPU operating conditions. As previously discussed, the existing radial wells have degraded over time and thus cannot perform at their full design capacity. The new radial well is scheduled to be completed and operational in May 2012. Although water being utilized for cooling tower make-up is projected to increase from current levels, the estimated EPU cooling tower makeup flow value of 27,860 gpm (62 cubic feet per second (cfs)) is less than the estimated 42,636

gpm (95 cfs) value identified in the GGNS FES; therefore, groundwater consumption remains lower than the value analyzed in the GGNS FES.

Public water supply wells in Claiborne County (excluding GGNS) are supplied by the Catahoula Formation with well depths ranging from 166 to 960 feet. Aside from GGNS Unit 1, the primary use of groundwater in Claiborne County is for public supply purposes with a small percentage used for domestic water, irrigation, and livestock. Within a two-mile radius of the plant site, essentially all groundwater is used for domestic purposes.

GGNS groundwater is supplied from the Mississippi River Alluvium (radial wells) and the Upland Complex (potable wells) aquifers. Residents within the vicinity of GGNS are served by CS&I Water Association which withdraws water from the Miocene aquifer. Since the GGNS withdraws groundwater from the Mississippi River Alluvium and Upland Complex aquifers, the Miocene aquifers, including the Catahoula Formation, are unaffected.

The impact to offsite groundwater users from the withdrawal of water by GGNS Unit 1 is limited by the recharge boundary created by the river, and thus, is not expected to extend to the west beyond the river. Based on estimates of the radius of anticipated drawdown of the GGNS radial wells, drawdown at the GGNS property boundaries would have limited impact on potential offsite use in the Mississippi River Alluvium aquifer. This is a conservative estimate of aquifer capacity impact, as aquifer recharge from sources other than the river (flooding and rainfall events) was not considered. GGNS's potable water wells are the closest wells withdrawing groundwater in the vicinity (although not from the Mississippi River Alluvium) and have operated to supply adequate water supply to the GGNS site without noticeable impact from the operation of the radial wells. There are no known withdrawals from the Mississippi River Alluvium aquifer other than GGNS Unit 1 between the Big Black River to the north, and Bayou Pierre River to the south.

Water rights and allocations of groundwater are regulated by MDEQ. Therefore, all existing GGNS Unit 1 groundwater withdrawals, including those from the radial wells, are regulated by a groundwater allocation permitting program. These permits were granted considering their identified potential impact on other uses in the area and considering those withdrawals in the recharge area of the Mississippi River Alluvium aquifer. Based on the above, there are no groundwater use conflicts between GGNS and other local groundwater users.

Approximately 40 percent of the GGNS site is bottomland, including forested, shrub, and emergent marsh wetlands. As stated above, the groundwater in the alluvium in the floodplain is in close hydraulic communication with the river. The groundwater contour figures reveal that the impact of the cone of depression surrounding the radial wells is dependent upon river stage. This impact is limited also by recharge to the alluvium derived from infiltration of precipitation, westward flow of groundwater across the terrace alluvium contact at the bluffs, and the flooding of the Mississippi River during high river stages. Thus, based on the localized influence of the drawdown zone surrounding the wells, the groundwater's hydraulic connection with the river, recharge from seasonal flooding and additional recharge from the Upland Terrace aquifer east of the bluffs, the impact of radial well groundwater withdrawal in the floodplain is of limited extent. Even though there is potentially greater impact to groundwater levels at the lowest river stages than at higher river stages, the low river stages are generally temporary. Therefore, the impact of the radial wells on nearby wetlands is minimal.

Plant operation at the proposed EPU power level is not expected to cause impacts significantly greater than current operations. As previously discussed, groundwater withdrawals would continue to be lower than the values analyzed in the GGNS FES as a result of EPU and continued operational activities. The installation of an additional radial well is expected to reduce the per-well withdrawal rates without an increase in overall groundwater impacts. No major construction is planned, so additional groundwater withdrawals will not be required. Based on the above, the NRC staff concludes that the EPU will not have a significant impact on groundwater in the underlying aquifers, and operation under EPU conditions would not cause a water use conflict with other groundwater users in the GGNS area.

Aquatic Resources Impacts

The potential impacts to aquatic biota from the proposed action could include thermal and chemical discharge effects. GGNS does not have an intake structure that withdraws surface water directly from a body of water, therefore, no entrainment or impingement of organisms would occur.

GGNS uses groundwater from a series of radial wells to supply its plant service water system, as discussed in the Water Use Impacts section. The circulating water system is a closed system utilizing a natural draft cooling tower and a mechanical draft auxiliary cooling tower. The natural draft cooling tower is designed to operate alone or in conjunction with the auxiliary cooling tower to dissipate all excess heat removed from the main condensers. Additional cooling units will be added to the auxiliary cooling tower, as discussed in the Land Use and Aesthetics section. Makeup water, to compensate for drift, blowdown, and evaporation losses from the cooling towers, is supplied from the plant service water system by means of the radial wells. A new radial well will be installed to handle the increase in heat load associated with the EPU, as discussed in the Water Use section.

The circulating water system is designed to supply the main condenser with cooling water at temperatures ranging from 2.8 degrees Celsius (°C) (37 degrees Fahrenheit (°F)) to 36.1 °C (97 °F) when the mechanical draft auxiliary cooling tower is not in service, and less than 32.2 °C (90 °F) with the natural draft and auxiliary cooling towers both in service. The licensee states that the auxiliary cooling towers remain in service year round, with the exception of a short period (i.e., hours) when they are taken out of service for cleaning. Therefore, water being supplied to the condenser is anticipated to be less than 32.2 °C (90 °F) year round.

Thermal effluents associated with cooling tower blowdown are combined with other plant effluents and discharged into the Mississippi River. The conditions associated with thermal discharges as outlined in GGNS's MDEQ NPDES permit state that the receiving water shall not exceed a maximum water temperature change of 2.8 °C (5.0 °F) and that the maximum water temperature shall not exceed 32.2 °C (90 °F), except when ambient temperatures approach or exceed that number.

GGNS is required by the MDEQ NPDES Permit to conduct thermal monitoring during the winter and summer months preceding the submittal year of the permit renewal application and include those results in the submittal. Based on previous years of operational experience, GGNS has not violated the thermal conditions outlined in the permit.

Based on the above, the NRC staff finds that although the heat load would increase as a result of the proposed EPU, the thermal discharge associated with GGNS operations would continue to remain at or slightly below current operating temperatures due to the additional cooling units being installed in the auxiliary cooling tower. As stated by the licensee, the auxiliary cooling towers operate in conjunction with the natural draft cooling tower year round. Consequently, the temperature of the cooling water being supplied to the condenser is not increasing, which ensures that the thermal conditions outlined in the GGNS MDEQ NPDES permit continue to be met. Therefore, the NRC staff concludes there would be no significant adverse impacts to aquatic biota from thermal discharges.

The plant service water system for GGNS is treated with sodium hypochlorite and biocides to control the pH in the coolant, to control scale, to control corrosion, and to clean and defoul the condenser. The liquid wastes produced from this process are combined with cooling water discharges in accordance with the site's MDEQ NPDES permit and discharged into the Mississippi River. Due to the additional cooling units being added to the auxiliary cooling tower, additional sodium hypochlorite injection will be needed to control biological fouling effectively. However, the liquid waste stream is dechlorinated with sodium bisulfite prior to being discharged to the Mississippi River. Consequently, effluent concentrations would continue to be below the NPDES permit limits specified by MDEQ. The licensee has noted that it will maintain compliance with the MDEQ NPDES permit held currently by the plant as a function of the proposed EPU. Therefore, the NRC staff concludes there would be no significant adverse impacts to aquatic biota from chemical discharges.

Dredging activities could occur in the existing barge slip area to accommodate delivery of transformers and other heavy equipment associated with the proposed EPU if use of the Claiborne County Port facility is determined to be infeasible from an economical and technological standpoint. Any refurbishment activities associated with the barge slip would occur in an area that would be managed under a Section 404 Permit issued by USACE. Dredging of the barge slip, if necessary, will be coordinated by the licensee with the USACE and conducted in accordance with the USACE's Section 404 permitting process, which involves a site-specific evaluation of potential environmental impacts and appropriate mitigation measures. Based on the above, the NRC staff concludes there would be no significant adverse impacts to aquatic biota from possible dredging activities.

Terrestrial Resources Impacts

The GGNS site is bisected by a prominent bluff line that runs parallel to the Mississippi River. Areas below the bluff line are seasonally flooded, except for two oxbow lakes which are permanently inundated and are considered wetland areas. Above the bluff line, the two prominent habitat types are upland field and upland forest with the vast majority upland forest. One small area of wetland has been defined on the north side of the plant as permanently flooded. Most of the previously developed areas are in upland habitat; however, approximately 400 acres of upland forest remains on-site.

The impacts that could potentially affect terrestrial resources include loss of habitat, construction and refurbishment-related noise and lighting, and sediment transport or erosion. Most of the activities associated with the EPU would occur on the developed portion of the site, would not directly affect any natural terrestrial habitats, and would not result in loss of habitat. As discussed in Land Use and Aesthetic Impacts section above, activities associated with installation of the new radial well would be managed in accordance with the Section 404 Permit and MDEQ's stormwater permitting program (Permit Number MSR15) as appropriate. Although there is no habitat present on the Heavy Haul Road, refurbishment activities associated with the road would be managed in accordance with the terms and conditions in State and Federal permits. Noise and lighting would not impact terrestrial species beyond what would be experienced during normal operations because refurbishment and construction activities would take place during outage periods, which are already periods of heightened activity. Based on the above, the NRC staff concludes that the proposed EPU would have no significant effect on terrestrial resources.

Threatened and Endangered Species Impacts

The licensee corresponded with the U.S. Fish and Wildlife Service (USFWS) during the preparation of the Environmental Report for the EPU to ensure that the proposed EPU would not adversely affect any species protected under the Endangered Species Act. The following Table 1 identifies federally listed and candidate species that are in the vicinity of GGNS.

TABLE 1—FEDERALLY LISTED SPECIES IN THE VICINITY OF GRAND GULF NUCLEAR STATION

Scientific	Name	Status [a]
Birds:		
Picoides borealis	red-cockaded woodpecker	E
Sterna antillarum	least tern (interior pop.)	E
Clams:		
Potamilus capax	fat pocketbook	E
Quadrula cylindrica cylindrica	rabbitsfoot	C
Fish:		
Etheostoma rubrum	bayou darter	T
Acipenser oxyrinchus desoto	gulf sturgeon	T
Scaphirhynchus albus	pallid sturgeon	E
Mammals:		
Ursus americanus luteolus	Louisiana black bear	T

[a] C = candidate; E = endangered; T = threatened.

Data source: [FWS] U.S. Fish and Wildlife Service. 2011. Find Endangered Species Database. Available at <*http://www.fws.gov/endangered/*> (accessed 13 December 2011).

As discussed in the Land Use and Aesthetic Impacts section, the only EPU activities involving land disturbance is the installation of a new radial well, Heavy Haul Road improvements, and potential dredging activities in the barge slip. These activities would be handled in accordance with the terms and conditions in State and Federal permits.

The licensee states that procedures are in place at GGNS to ensure that threatened and endangered species would be adequately protected, if present, during the outage and during plant operations. Any traffic and worker activity on the plant site during its 2012 refueling outage would be on the developed portion of the site and would not affect any federally listed species.

As stated above, the licensee consulted with the USFWS regarding threatened and endangered species in the vicinity of GGNS. No issues were identified that would impact any of the federally listed species as a result of the proposed EPU. Therefore, the NRC staff concludes that the proposed EPU would have no significant impacts on any Federally listed threatened or endangered species for the proposed action.

Historic and Archaeological Resources Impacts

The licensee states that at the recommendation of the Mississippi Department of Archives and History (MDAH), a Phase I archaeological survey was conducted in 2007 on two onsite study areas. Eleven archaeological sites and eight isolated finds/small artifact scatters were identified during this survey. One historic site within the study area and located south of the plant in a wooded area, was identified as having the potential to be eligible for the National Register of Historic Places (NRHP). The remaining sites were determined to be ineligible for listing on the NRHP. The MDAH required no further actions from GGNS provided that no construction activities occurred in this specific area.

As discussed in Land Use and Aesthetic Impacts section, the only EPU activities involving land disturbance is the installation of a new radial well, Heavy Haul Road improvements, and potential dredging activities in the barge slip area. Entergy has a procedure in place, applicable to all of its power plants, for management of cultural resources ahead of any future ground-disturbing activities. This procedure, which requires reviews, investigations, and consultations, as needed, ensures that existing or potentially existing cultural resources are adequately protected and assists Entergy in meeting State and Federal expectations.

As previously discussed, EPU-related plant modifications would take place within existing buildings and facilities at GGNS, except for the addition of the cooling units being added to the auxiliary cooling tower which will be installed on an existing foundation. Since ground disturbance or construction-related activities would not occur in any areas with the potential to be eligible for the NRHP, and that Entergy has procedures in place for management of cultural resources, the NRC staff concludes that there would be no significant impact from the proposed EPU on historic and archaeological resources in the vicinity of GGNS Unit 1.

Socioeconomic Impacts

Potential socioeconomic impacts from the proposed EPU include temporary increases in the size of the workforce at GGNS, and the associated increased demand for goods, public services, and housing in the region. The proposed EPU also could generate increased tax revenues for the State and surrounding counties.

Currently, approximately 690 full-time employees work at GGNS. During regularly scheduled refueling outages, the workforce is typically increased by additional 700–900 persons. Refueling outages usually last 25–30 days every 18 months, although GGNS plans to change to a 24-month refueling cycle in the future. Entergy estimates that operating at the proposed EPU power level would not affect the size of the regular workforce. The 2012 outage workforce will be larger than previous outages due to the EPU modifications but would be of short duration. Once EPU-related plant modifications have been completed, the size of the refueling outage workforce at GGNS would return to normal levels and would remain similar to pre-EPU levels, with no significant increases during future refueling outages. Entergy expects most of the temporary workers expected for the EPU related work will temporarily reside in Claiborne County. This will result in short-term increases in the local population along with increased demands for public services and housing. Because plant modification work would be short term and temporary, most workers are expected to stay in available rental homes, apartments, mobile homes, and camper-trailers. The 2010 American Community Survey 1-year estimate for vacant housing units reported 783 vacant housing units in Claiborne County; that could potentially ease the demand for local rental housing. Therefore, the NRC expects that the temporary increase in plant employment for a short duration would have little or no noticeable effect on the availability of housing in the region.

The additional number of outage workers and material and equipment deliveries needed to support EPU-related plant modifications would cause short-term level of service impacts (restricted traffic flow and higher incident rates) on secondary roads in the immediate vicinity of GGNS. As EPU-related plant modifications would occur during a normal refueling outage, there could be noticeable short-term (during certain hours of the day), level-of-service traffic impacts beyond what is experienced during normal outages.

Nuclear power plants in Mississippi currently pay the Mississippi Department of Revenue a sum based on the assessed value of the plant. Based upon this assessment, nuclear power plants are then taxed 2 percent of its assessed value, or $20,000,000, whichever is greater. GGNS currently pays $20,000,000 annually to the Mississippi Department of Revenue. Tax revenue is distributed in proportion to the amount of electric energy consumed by the retail customers in each county, with no county receiving an excess of 20 percent of the funds. Ten percent of the remainder of the tax payment is then transferred from the Mississippi Department of Revenue to the General Fund of the State. The increased property value of GGNS as a result of the EPU and increased power generation could affect future tax payments by GGNS.

Due to the short duration of EPU-related plant modification activities, there would be little or no noticeable effect on tax revenues generated by temporary workers residing in Claiborne County. In addition, GGNS is currently paying the maximum tax on the assessed value of the plant. Therefore, the NRC expects no significant socioeconomic impacts from EPU-related plant modifications and operations under EPU conditions in the vicinity of GGNS.

Environmental Justice Impacts

The environmental justice impact analysis evaluates the potential for disproportionately high and adverse human health and environmental effects on minority and low-income populations that could result from activities associated with the proposed EPU at GGNS. Such effects may include human health, biological, cultural, economic, or social impacts. Minority and low-income populations are subsets

of the general public residing around GGNS, and all are exposed to the same health and environmental effects generated from activities at GGNS.

NRC considered the demographic composition of the area within a 50-mile (mi) (80.5-kilometer (km)) radius of GGNS to determine whether minorities may be affected by the proposed action. The NRC examined the distribution of minority populations within 50 mi (80.5 km) of GGNS using the U.S. Census Bureau (USCB) data for 2010.

According to the 2010 Census data using the University of Missouri's Circular Area Profiling System, an estimated 316,387 people live within a 50-mi (80.5-km) radius of GGNS. Minority populations within 50 mi (80.5 km) comprise 53.2 percent (168,166 persons). The largest minority group was Black or African-American (approximately 157,707 persons or 49.8 percent), followed by Hispanic or Latino (of any race) (approximately 6,115 persons or 1.9 percent). Minority populations within Claiborne County comprise 85.2 percent of the total population with the largest minority group being Black or African-American at 84.6 percent.

NRC examined low-income populations within Claiborne County using the 2006–2010 American Community Survey 5-Year Estimates. According to census data, approximately 35 percent of the population (3,186 individuals) residing within Claiborne County was considered low-income, defined as living below the 2010 Federal poverty threshold. Approximately 27.6 percent of families were determined to be living below the Federal poverty threshold in Claiborne. The 2010 Federal poverty threshold was $22,314 for a family of four and $11,139 for an individual. The median household income for Claiborne County was approximately $24,150, which is 51 percent lower than the median household income (approximately $47,031) for Mississippi.

Potential impacts to minority and low-income populations would mostly consist of environmental and socioeconomic effects (*e.g.,* noise, dust, traffic, employment, and housing impacts). Radiation doses from plant operations after the EPU are expected to continue to remain well below regulatory limits.

Noise and dust impacts would be temporary and limited to onsite activities. Minority and low-income populations residing along site access roads could experience increased commuter vehicle traffic during shift changes. Increased demand for inexpensive rental housing during the EPU-related plant modifications could disproportionately affect low-income populations; however, due to the short duration of the EPU-related work and the availability of housing properties, impacts to minority and low-income populations would be of short duration and limited. According to the 2010 census information, there were approximately 783 vacant housing units in Claiborne County.

Based on this information and the analysis of human health and environmental impacts presented in this EA, the proposed EPU would not have disproportionately high and adverse human health and environmental effects on minority and low-income populations residing in the GGNS vicinity.

Non-Radiological Cumulative Impacts

The NRC considered potential cumulative impacts on the environment resulting from the incremental impact of the proposed EPU when added to other past, present, and reasonably foreseeable future actions. For the purposes of this analysis, past actions are related to the construction and licensing of GGNS Unit 1; present actions are related to current operations; and future actions are those that are reasonably foreseeable through the end of station operations, including operations following implementation of the EPU.

Entergy submitted a combined license application (COL) to the NRC for an Economic Simplified Boiling Water Reactor, designated as GGNS Unit 3, on February 27, 2008. On January 9, 2009, Entergy informed the NRC that it was considering alternate reactor design technologies and requested the NRC suspend its review effort until further notice. The application to build GGNS Unit 3 on the GGNS site is considered a reasonably foreseeable future action that is considered in this review. It is expected, however, that the proposed EPU, if approved, would be completed prior to the construction of any proposed new reactor. Thus, the cumulative impacts discussed in this section consider GGNS Unit 1 operations (under the EPU) combined with the environmental impacts from the proposed construction and operation of any new proposed unit.

It is important to note that submitting the COL application does not commit Entergy to build a new nuclear power unit and does not constitute approval of the proposal by the NRC. The COL application will be evaluated on its merits, and after considering and evaluating the environmental and safety implications of the proposal, the NRC will decide whether to approve or deny the license. Environmental impacts of constructing and operating a new unit will depend on their actual design characteristics, construction practices, and power plant operations. These impacts will be assessed by the NRC in a separate NEPA document. The cumulative impacts presented in this EA may differ from those impacts assessed for the COL application.

For some resource areas (e.g., air quality, water, aquatic, terrestrial resources, and threatened and endangered species), the contributory effect of ongoing actions within a region are regulated and monitored through a permitting process (e.g., NPDES and 401/404 permits under the Clean Water Act) under State or Federal authority. In these cases, impacts are appropriately managed as long as these actions are in compliance with their respective permits and conditions of certification.

Any new proposed reactor power unit, transmission lines, and related infrastructure improvements would be constructed and operated according to Federal and State regulations, permit conditions, existing procedures, and established best management practices. Nevertheless, wildlife may be destroyed or displaced during land clearing for any new proposed unit. Less mobile animals, such as reptiles, amphibians, and small mammals, would incur greater mortality than more mobile animals, such as birds. As construction activities end, habitats could be restored either naturally or through mitigation activities.

Terrestrial species and habitat could be affected by any new proposed unit's cooling system operations. New capacity for cooling and its placement will have to be determined. Also, any land needed for any new proposed units and any additional cooling capacity will need to be surveyed for historical and archaeological sites.

Socioeconomic impacts from the construction and operation of any proposed units would occur several years after the EPU. The large construction and operation workforces combined with ongoing operation of GGNS Unit 1 under the EPU would be expected to have a noticeable effect on socioeconomic conditions in local communities from the increased demand for temporary and permanent housing, public services (e.g., public schools), and increased traffic.

Non-Radiological Impacts Summary

As discussed above, the proposed EPU would not result in any significant non-radiological impacts. Table 2 summarizes the non-radiological

environmental impacts of the proposed EPU at GGNS.

TABLE 2—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS

Land Use	The proposed EPU is not expected to cause a significant impact on land use conditions and aesthetic resources in the vicinity of the GGNS.
Air Quality	The proposed EPU is not expected to cause a significant impact to air quality.
Water Use	The proposed EPU is not expected to cause impacts significantly greater than current operations. No significant impact on groundwater or surface water resources.
Aquatic Resources	The proposed EPU is not expected to cause impacts significantly greater than current operations. No significant impact to aquatic resources due to additional chemical or thermal discharges.
Terrestrial Resources	The proposed EPU is not expected to cause impacts significantly greater than current operations. No significant impact to terrestrial resources.
Threatened and Endangered Species	The proposed EPU would not cause impacts significantly greater than current operations. No significant impact to Federally listed species.
Historic and Archaeological Resources	No significant impact to historic and archaeological resources on site or in the vicinity of the GGNS.
Socioeconomics	No significant socioeconomic impacts from EPU-related temporary increase in workforce.
Environmental Justice	No disproportionately high and adverse human health and environmental effects on minority and low-income populations in the vicinity of the GGNS site.
Cumulative Impacts	The proposed EPU would not cause impacts significantly greater than current operations.

Radiological Impacts

Radioactive Gaseous and Liquid Effluents and Solid Waste

GGNS Unit 1 uses waste treatment systems to collect, process, recycle, and dispose of gaseous, liquid, and solid wastes that contain radioactive material in a safe and controlled manner within NRC and EPA radiation safety standards. The licensee's evaluation of plant operation under the proposed EPU conditions shows that no physical changes would be needed to the radioactive gaseous, liquid, or solid waste systems.

Radioactive Gaseous Effluents

The gaseous waste management systems include the ventilation systems of normally and potentially radioactive components, building ventilation systems, the off-gas system, and the mechanical vacuum pump system. The licensee's evaluation concluded that the proposed EPU is expected to increase the production and activity of gaseous effluents approximately 13 percent; however, the increase would be below the design basis values the system is designed to handle. The licensee's evaluation concluded that the proposed EPU would not change the radioactive gaseous waste system's design function and reliability to safely control and process the waste. The projected gaseous releases following implementation of the EPU would remain within the values analyzed in the FES for GGNS Unit 1. The existing equipment and plant procedures that control radioactive releases to the environment will continue to be used to maintain radioactive gaseous releases within the dose limits of 10 CFR 20.1302 and the as low as is reasonably achievable (ALARA) dose objectives in Appendix I to 10 CFR Part 50.

Radioactive Liquid Effluents

The liquid waste management system collects, processes, and prepares radioactive liquid waste for disposal. Radioactive liquid wastes include liquids from various equipment drains, floor drains, chemical wastes, and miscellaneous plant equipment subsystems, and alternative liquid radioactive waste processing equipment. Entergy is installing a condensate full flow filter (CFFF)—iron control system upstream of the condensate demineralizers to reduce the corrosion product loading on the demineralizer resins. The addition of iron control to the CFFF would prevent iron from being deposited on the demineralization resin. The amount of liquid waste generated by the condensate demineralizer system is expected to remain unchanged or even decrease. The licensee's evaluation shows that the proposed EPU implementation would not significantly increase the inventory of liquid normally processed by the liquid waste management system. This is because the system functions are not changing, and the volume inputs remain the same. The proposed EPU would result in a 13 percent increase in the equilibrium radioactivity in the reactor coolant which in turn would impact the concentrations of radioactive nuclides in the liquid waste disposal systems.

Since the composition of the radioactive material in the waste and the volume of radioactive material processed through the system are not expected to significantly change, the current design and operation of the radioactive liquid waste system will accommodate the effects of the proposed EPU. The projected liquid effluent release following EPU implementation would remain within the values analyzed in the FES for GGNS Unit 1. The existing equipment and plant procedures that control radioactive releases to the environment will continue to be used to maintain radioactive liquid releases within the dose limits of 10 CFR 20.1302 and ALARA dose standards in Appendix I to 10 CFR part 50.

Radioactive Solid Wastes

The solid radwaste system is designed to provide solidification and packaging for radioactive wastes that are produced during shutdown, startup, and normal operation, and to store these wastes until they are shipped offsite for burial. Solid radwaste is processed on a batch basis and would increase slightly, resulting in an increase in batch processing. The licensee's evaluation concluded that the annual volume of solid waste is expected to increase from 152.83 cubic meters (m^3) at current licensed thermal power to 153.65 m^3 per year, or 0.82 m^3 per year. Although EPU implementation increases the amount of solid waste produced, the design capability of the solid radwaste system and the total volume capacity for handling solid waste are unaffected, and the system will be able to handle the additional waste without any modifications. The equipment is

designed and operated to process the waste into a form that minimizes potential harm to the workers and the environment. Waste processing areas are monitored for radiation, and there are safety features to ensure worker doses are maintained within regulatory limits. The proposed EPU would not generate a new type of waste or create a new waste stream.

The licensee manages low level radioactive waste (LLRW) contractually with an offsite vendor and expects to continue to ship LLRW offsite for processing and disposal. Entergy currently transports radioactive waste to licensed processing facilities in Tennessee, including Duratek (owned by EnergySolutions) or Race (owned by Studsvik), where the wastes are processed prior to being sent for disposal at EnergySolutions in Clive, Utah.

Based on the above, the NRC staff concludes that the impact from the proposed EPU on the management of radioactive solid waste would not be significant.

Occupational Radiation Dose at EPU Power Levels

The licensee stated that the in-plant radiation sources are expected to increase approximately linearly with the proposed increase in core power level. To protect the workers, the licensee's radiation protection program monitors radiation levels throughout the plant to establish appropriate work controls, training, temporary shielding, and protective equipment requirements so that worker doses will remain within the dose limits of 10 CFR part 20 and ALARA.

The licensee states that GGNS Unit 1 has been designed using an extremely conservative basis for water and steam radionuclide concentrations such that changes in actual concentrations as a result of EPU are well within the original design limits. Inside containment, the radiation levels near the reactor vessel are assumed to increase by 13 percent. However, the reactor vessel is inaccessible during operation, and because of the margin in the shielding around the reactor vessel, an increase of 13 percent would not measurably increase occupational doses during power operation. The radiation levels due to spent fuel are anticipated to increase by 13 percent. Expected increases in these values would occur primarily in fuel handling operations during refueling outages. However, a review of existing radiation zoning design concluded that no changes in the radiation zone designations or shielding requirements would need to be made as a result of EPU, and operation under EPU conditions would have no significant effect on occupational and onsite radiation exposure.

Based on the above, the NRC staff concludes that the proposed EPU is not expected to significantly affect radiation levels within the plants and, therefore, there would not be a significant radiological impact to the workers.

Offsite Doses at EPU Power Levels

The licensee states that normal operational gaseous activity levels may increase slightly. The increase in activity levels is generally proportional to the percentage increase in core thermal power, which is approximately 13 percent. However, this slight increase does not affect the large margin to the offsite dose limits established by 10 CFR part 20, allowing GGNS to operate well below the regulatory limits even at the higher power level.

The sources of offsite dose to members of the public from GGNS Unit 1 are radioactive gaseous and liquid effluents and direct radiation. As previously discussed, operation at the proposed EPU conditions will not change the radioactive waste management systems' abilities to perform their intended functions. Also, there would be no change to the radiation monitoring system and procedures used to control the release of radioactive effluents in accordance with NRC radiation protection standards in 10 CFR part 20 and Appendix I to 10 CFR part 50.

Based on the above, the NRC staff concluded that the offsite radiation dose to members of the public from the proposed EPU would continue to be within the NRC and EPA regulatory limits and, therefore, would not be significant.

Spent Nuclear Fuel

Spent fuel from GGNS Unit 1 is stored in the plant's spent fuel pool and in dry casks in the independent spent fuel storage installation. The current typical average enrichment of a batch of fuel at GGNS is approximately 4 percent by weight uranium-235. The additional energy requirements for the EPU are met by an increase in fuel enrichment, an increase in the reload fuel batch size, and/or changes in the fuel loading pattern to maintain the desired plant operating cycle length. The equilibrium core evaluated for the EPU has an average enrichment well below 4.5 percent uranium-235 by weight. Entergy's EPU evaluation also considered a possible future change to a 24-month refueling cycle; the combination of the EPU and the longer cycle length could result in an increase in fuel bundle assembly size from 312 to about 380 assemblies. The maximum average burnup level of any fuel rod would continue to be less than 62,000 megawatt-days per metric tonne (MWd/MTU), and reload design goals would maintain the GGNS Unit 1 fuel cycles within the burnup and enrichment limits bounded by the impacts analyzed in 10 CFR part 51, Table S–3—Table of Uranium Fuel Cycle Environmental Data, and Table S–4—Environmental Impact of Transportation of Fuel and Waste to and from One Light-Water-Cooled Nuclear Power Reactor, as supplemented by NUREG–1437, Volume 1, Addendum 1, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Main Report. Section 6.3—Transportation Table 9.1, Summary of findings on NEPA issues for license renewal of nuclear power plants.'' Therefore, the NRC staff concludes that there would be no significant impacts resulting from spent nuclear fuel.

Postulated Design-Basis Accident Doses

Postulated design-basis accidents are evaluated by both the licensee and the NRC to ensure that GGNS Unit 1 can withstand normal and abnormal transients and a broad spectrum of postulated accidents without undue hazard to the health and safety of the public.

The NRC staff is reviewing the applicant's analyses to independently verify the applicant's calculated doses under accident conditions. The NRC staff's evaluation results will be contained in the safety evaluation that will be issued concurrently with the proposed EPU amendment, if so approved by the NRC staff. However, for the purpose of this EA, the NRC staff concludes that, based on the information provided by the licensee, the proposed EPU would not significantly increase the radiological consequences of postulated accidents.

Radiological Cumulative Impacts

The radiological dose limits for protection of the public and workers have been developed by the NRC and EPA to address the cumulative impact of acute and long-term exposure to radiation and radioactive material. These dose limits are codified in 10 CFR Part 20 and 40 CFR part 190.

The cumulative radiation dose to the public and workers are required to be within the limits set forth in the regulations cited above. The public dose limit of 25 millirem (mrem) (0.25 millisievert (mSv)) in 40 CFR part 190 applies to all reactors that may be on a

site and also includes any other nearby nuclear facilities. Currently, there is no other nuclear power reactor or uranium fuel cycle facility located near GGNS Unit 1. However, as previously discussed, Entergy is considering the construction of an additional nuclear power reactor at the GGNS site. The NRC staff reviewed several years of radiation dose data contained in the licensee's annual radioactive effluent release reports for GGNS Unit 1. The data demonstrate that the dose to members of the public from radioactive effluents is within the limits of 10 CFR part 20 and 40 CFR Part 190. To evaluate the projected dose at EPU power levels for GGNS Unit 1, the NRC staff increased the actual dose data contained in the reports by 13 percent. The projected doses for GGNS Unit 1 at EPU power level remained within regulatory limits. The NRC staff expects continued compliance with NRC's and EPA's public dose limits during operation at the proposed EPU power level and at the proposed new reactor, if it is constructed and operated. Therefore, the NRC staff concludes that there would not be a significant cumulative radiological impact to members of the public from increased radioactive effluents from GGNS Unit 1 at the proposed EPU operation and the proposed new reactor.

As previously discussed, the licensee has a radiation protection program that maintains worker doses within the dose limits in 10 CFR part 20 during all phases of GGNS Unit 1 operations. The NRC staff expects continued compliance with NRC's occupational dose limits during operation at the proposed EPU power level and at the proposed new reactor, if it is constructed and operated.

Therefore, the NRC staff concludes that operation of GGNS Unit 1 at the proposed EPU power level and the proposed new reactor would not result in a significant impact to the worker's cumulative radiological dose.

Radiological Impacts Summary

As discussed above, the proposed EPU would not result in any significant radiological impacts. Table 3 summarizes the radiological environmental impacts of the proposed EPU at GGNS Unit 1.

TABLE 3—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS

Radioactive Gaseous Effluents	Amount of additional radioactive gaseous effluents generated would be handled by the existing system.
Radioactive Liquid Effluents	Amount of additional radioactive liquid effluents generated would be handled by the existing system.
Occupational Radiation Doses	Occupational doses would continue to be maintained within NRC limits.
Offsite Radiation Doses	Radiation doses to members of the public would remain below NRC and EPA radiation protection standards.
Radioactive Solid Waste	Amount of additional radioactive solid waste generated would be handled by the existing system.
Spent Nuclear Fuel	The spent fuel characteristics will remain within the bounding criteria used in the impact analysis in 10 CFR Part 51, Table S–3, and Table S–4.
Postulated Design- Basis Accident Doses.	Calculated doses for postulated design-basis accidents would remain within NRC limits.
Cumulative Radiological	Radiation doses to the public and plant workers would remain below NRC and EPA radiation protection standards.

Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed EPU (*i.e.,* the ''no-action'' alternative). Denial of the application would result in no change in the current environmental impacts. However, if the EPU were not approved for GGNS Unit 1, other agencies and electric power organizations may be required to pursue other means, such as fossil fuel or alternative fuel power generation, to provide electric generation capacity to offset future demand. Construction and operation of such a fossil-fueled or alternative-fueled plant could result in impacts in air quality, land use, and waste management greater than those identified for the proposed EPU for GGNS Unit 1.

Alternative Use of Resources

The action does not involve the use of any different resources than those previously considered in the GGNS FES.

IV. Finding of No Significant Impact

On the basis of the details provided in the EA, the NRC concludes that granting the proposed EPU license amendment is not expected to cause impacts significantly greater than current operations. Therefore, the proposed action of implementing the EPU for GGNS Unit 1 will not have a significant effect on the quality of the human environment because no significant permanent changes are involved, and the temporary impacts are within previously disturbed areas at the site and the capacity of the plant systems. As discussed in the EA, if any new land disturbances are required to support the proposed EPU, those activities will be conducted in accordance with State and Federal permits to ensure the potential impacts are not significant. Accordingly, the NRC has determined it is not necessary to prepare an environmental impact statement for the proposed action. A final determination to prepare an environmental impact statement or a final finding of no significant impact will not be made until the public comment period expires.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 2nd day of May 2012.

Alan B. Wang,

Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–11423 Filed 5–10–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Project No. 753; NRC–2012–0019]

Model Safety Evaluation for Plant-Specific Adoption of Technical Specifications Task Force Traveler TSTF–432, Revision 1, ''Change in Technical Specifications End States (WCAP–16294)'' Using the Consolidated Line Item Improvement Process

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is announcing the availability of the model safety evaluation (SE) for plant-specific adoption of Technical Specifications (TSs) Task Force (TSTF) Traveler TSTF–

432, Revision 1, ''Change in Technical Specifications End States (WCAP–16294).''

The proposed change revises the Improved Standard Technical Specification (ISTS), NUREG–1431, ''Standard Technical Specifications Westinghouse Plants,'' to permit, for some systems, entry into a hot shutdown (Mode 4) end state rather than a cold shutdown (Mode 5) end state. The model SE will facilitate expedited approval of plant-specific adoption of TSTF–432, Revision 1. This TS improvement is part of the consolidated line item improvement process.

ADDRESSES: Please refer to Docket ID NRC–2012–0019 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0019. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select *''ADAMS Public Documents''* and then select *''Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* TSTF–432, Revision 1, is available in ADAMS under Accession No. ML103360003; the model application is available under ADAMS Accession No. ML113202614; and the model SE for plant-specific adoption of TSTF–432, Revision 1, is available under ADAMS Accession No. ML120200384. The NRC staff disposition of comments received to the Notice of Opportunity for Public Comment announced in the **Federal Register** on January 30, 2012 (77FR4586), is available under ADAMS Accession No. ML12072A159.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Ms. Michelle C. Honcharik, Senior Project Manager, Licensing Processes Branch, Mail Stop: O–12 D1, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–1774 or email at *Michelle.Honcharik@nrc.gov* or Ms. Kristy Bucholtz, Technical Specifications Branch, Mail Stop: O–7 C2A, Division of Safety Systems, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–1295 or email; *Kristy.Bucholtz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

TSTF–432, Revision 1, is applicable to Westinghouse-designed pressurized water reactor (PWR) plants. The proposed changes revise the ISTS to permit, for some systems, entry into a hot shutdown (Mode 4) end state rather than a cold shutdown (Mode 5) end state. These changes are associated with the implementation of Topical Report WCAP–16294–NP–A, Revision 1, ''Risk-Informed Evaluation of Changes to Technical Specification Required Action Endstates for Westinghouse NSSS [nuclear steam supply system] PWRs,'' dated June 2010 (ADAMS Package Accession No. ML103430264). TS Bases changes that reflect the proposed changes are included.

The NRC staff has reviewed the model application for TSTF–432 and has found it acceptable for use by licensees. Licensees opting to apply for this TS change are responsible for reviewing the NRC staff SE and the applicable technical bases, providing any necessary plant-specific information, and assessing the completeness and accuracy of their license amendment request (LAR). The NRC will process each amendment application responding to the Notice of Availability according to applicable NRC rules and procedures.

The proposed changes do not prevent licensees from requesting an alternate approach or proposing changes other than those proposed in TSTF–432, Revision 1. However, significant deviations from the approach recommended in this notice or the inclusion of additional changes to the license will require additional NRC staff review. This may increase the time and resources needed for the review or result in NRC staff rejection of the LAR. Licensees desiring significant deviations or additional changes should instead submit an LAR that does not claim to adopt TSTF–432, Revision 1.

Dated at Rockville, Maryland, this 2nd day of May 2012.

For the Nuclear Regulatory Commission.

John R. Jolicoeur,

Chief, Licensing Processes Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–11425 Filed 5–10–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2011–0256]

Aging Management of Stainless Steel Structures and Components in Treated Borated Water

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim staff guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing License Renewal Interim Staff Guidance (LR–ISG), LR–ISG–2011–01, ''Aging Management of Stainless Steel Structures and Components in Treated Borated Water.'' This LR–ISG revises the guidance in the Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants (SRP–LR) and Generic Aging Lessons Learned (GALL) Report for the aging management of stainless steel structures and components exposed to treated borated water. The NRC published Revision 2 of the SRP–LR and GALL Report in December 2010, and they are available in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession Nos. ML103490041 and ML103490036, respectively.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *ADAMS:* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The LR–ISG–2011–01 is available under ADAMS Accession No. ML12034A047.

• *Federal Rulemaking Web Site:* Public comments and supporting materials related to this final rule can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0256. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*

• *NRC's Interim Staff Guidance Web Site:* LR–ISG documents are also available online under the ''License Renewal'' heading at *http://www.nrc.gov/reading-rm/doc-collections/#int.*

FOR FURTHER INFORMATION CONTACT: Dr. John Wise, Division of License Renewal, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8489, or email: *John.Wise@nrc.gov,* or Ms. Evelyn Gettys, Division of License Renewal, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–001; telephone: 301–415–4029, or email: *Evelyn.Gettys@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Background Information

The NRC issues LR–ISGs to communicate insights and lessons learned and to address emergent issues not covered in license renewal guidance documents, such as the GALL Report and SRP–LR. In this way, the NRC staff and stakeholders may use the guidance in an LR–ISG document before it is incorporated into a formal license renewal guidance document revision. The NRC staff issues LR–ISGs in accordance with the LR–ISG Process, Revision 2 (ADAMS Accession No. ML100920158), for which a notice of availability was published in the **Federal Register** on June 22, 2010 (75 FR 35510).

The NRC staff has determined that existing guidance in the SRP–LR and GALL Report may not adequately address aging management of stainless steel structures and components exposed to treated borated water. Specifically, for pressurized water reactors, the guidance inappropriately credits boron as a corrosion inhibitor in place of other aging management activities. As a result, aging effects such as loss of material, cracking, and reduction of heat transfer may not be adequately managed. The staff has revised the guidance in the SRP–LR and GALL Report to align the guidance for treated borated water with that for treated (non-borated) water. The revisions include adding the One-Time Inspection program to verify the effectiveness of the Water Chemistry program to manage loss of material and cracking of stainless steel structures and components exposed to treated borated water and adding reduction of heat transfer due to fouling as an aging effect requiring management for stainless steel heat exchanger tubes exposed to treated borated water.

On November 8, 2011, the NRC staff issued a **Federal Register** notice (76 FR 69292) to request public comments on draft LR–ISG–2011–01 (ADAMS Accession No. ML112360626). In response, the NRC received comments from the Nuclear Energy Institute by letter dated December 13, 2011 (ADAMS Accession No. ML11350A112) and Exelon Generation Company, LLC by letter dated December 14, 2011 (ADAMS Accession No. ML11353A424). The Nuclear Energy Institute and Exelon provided similar comments suggesting the expansion of the new guidance to additional components for aging management of loss of material and cracking, but also suggesting the withdrawal or revision of the new guidance for management of reduction of heat transfer in heat exchangers.

The staff incorporated the comments regarding the expansion of the new guidance to additional components for management of loss of material and cracking, because the staff considered these changes as providing important clarity to license renewal applicants. However, the staff did not incorporate the comments regarding the withdrawal or revision of the new guidance for heat exchangers. The comments regarding the heat exchanger guidance were that the proposed one-time inspection was either not necessary due to lack of operating experience with fouling of heat exchangers in the chemical and volume control system, or not an appropriate aging management method due to the potential for inspection personnel to be exposed to significant radiation. The staff considers the one-time inspection approach as appropriate for components with limited operating experience of age-related degradation. If age-related degradation were known, the GALL Report One-Time Inspection program recommends a periodic inspection approach. Also, the one-time inspection guidance does not preclude a license renewal applicant from proposing and justifying other aging management approaches that minimize dosage. For these reasons, the staff chose not to eliminate the new guidance for heat exchangers.

The final LR–ISG–2011–01 is approved for NRC staff and stakeholder use and will be incorporated into the NRC's next formal license renewal guidance document revision.

Backfitting and Issue Finality

Issuance of this final LR–ISG does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in Part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' of 10 CFR. As discussed in the ''Backfitting Discussion'' section of final LR–ISG–2011–01, the LR–ISG is directed to holders of operating licenses or combined licenses who are currently in the license renewal process. The LR–ISG is not directed to holders of operating licenses or combined licenses until they apply for license renewal. The LR–ISG is also not directed to licensees who already hold renewed operating or combined licenses.

Dated at Rockville, Maryland, this 3rd day of May, 2012.

For the Nuclear Regulatory Commission.

Melanie A. Galloway,

Acting Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–11424 Filed 5–10–12; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Wednesday, May 9, 2012 at 10:30 a.m.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions as set forth in 5 U.S.C. 552b(c)(2), 4), (6) and (8) and 17 CFR 200.402(a)(2), (4), (6) and (8), permit consideration of the scheduled matters at the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

Commissioner Aguilar, as duty officer, voted to consider the item listed for the Closed Meeting in closed session, and determined that no earlier notice thereof was possible.

The subject matter of the May 9, 2012 Closed Meeting will be: An examination of a financial institution; and a personnel matter.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted

or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: May 9, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–11584 Filed 5–9–12; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66930; File No. SR–NYSEArca–2012–18]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving a Proposed Rule Change To List and Trade Shares of the APMEX Physical–1 oz. Gold Redeemable Trust Pursuant to NYSE Arca Equities Rule 8.201

May 7, 2012.

I. Introduction

On March 5, 2012, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade Units (''Units'') of the APMEX Physical–1 oz. Gold Redeemable Trust (the ''Trust'') pursuant to NYSE Arca Equities Rule 8.201. The proposed rule change was published for comment in the **Federal Register** on March 26, 2012.[3] The Commission received no comment letters regarding the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposal

The Exchange proposes to list and trade Units [4] under NYSE Arca Equities Rule 8.201. APMEX Precious Metals Management Services, Inc. is the manager of the Trust (''Manager'').[5] Computershare Trust Company of Canada is the trustee of the Trust (''Trustee''). RBC Dexia Investor Services (''RBC Dexia'') [6] is the custodian of the Trust (''Custodian'') [7] and the valuation agent of the Trust (''Valuation Agent'').

The Trust will issue Units in an initial public offering.[8] The Trust may not issue additional Units following the completion of the initial public offering except under certain conditions. NYSE Arca will require that a minimum of 1,000,000 Units be outstanding at the start of trading.[9] NYSE Arca represents that the Units satisfy the requirements of NYSE Arca Equities Rule 8.201 and thereby qualify for listing and trading on the Exchange.[10]

The Trust's investment objective is to invest and hold substantially all of its assets in 1 oz. gold coins. The Trust will hold 1 oz. American Gold Eagle bullion coins and 1 oz. Canadian Gold Maple Leaf bullion coins, and is permitted to purchase 1 oz. gold bullion bars and rounds. The Trust intends to hold highly liquid investments (consisting of short-term certificates of deposit or U.S. Government securities) or cash in an amount equal to approximately three percent of its total net assets generally to pay expenses and cash redemptions.

The Units will be redeemable weekly at the option of the holder for 1 oz. gold coins or for cash subject to certain conditions. Generally, units redeemed for 1 oz. gold coins will be entitled to receive a redemption price equal to 100% of the aggregate net asset value (''NAV'') of the redeemed Units determined at 4 p.m., Eastern time, on the Thursday on which NYSE Arca and/or the Toronto Stock Exchange (''TSX'') is open for trading for the week in respect of which the redemption request is processed, or the weekly redemption date and time, less the redemption expenses, or the gold redemption amount. Redemption requests for 1 oz. gold coins must be for a minimum redemption amount of at least $10,000.

Units will be redeemable on a monthly basis for cash. Units redeemed for cash will receive a redemption price equal to 95% of the lesser of (i) the volume-weighted average trading price of the Units traded on NYSE Arca or, if trading has been suspended on NYSE Arca, the trading price of the Units traded on the TSX, for the last five days on which the respective exchange is open for trading during the month in which the redemption request is processed; or (ii) the NAV of the redeemed Units as of 4 p.m., Eastern time, on the last day of the month on which NYSE Arca is open for trading during the month in which the redemption request is processed (in each case, less any applicable taxes). The Trust will retain the remaining 5% of the value of the Units.

Additional information can be found in the Notice and in the Registration Statement regarding: the Trust; the Units; the Trust's investment objectives, strategies, policies, and restrictions; fees and expenses; creation and redemption of Units; the gold bullion market and the 1 oz. gold coins; availability of information; trading rules and halts; and surveillance procedures.[11]

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act [12] and the rules and regulations thereunder applicable to a national securities exchange.[13] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[14] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In addition, the Commission finds that the proposal to list and trade Units

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 66627 (March 20, 2012), 77 FR 17539 (''Notice'').

[4] Each Unit will represent an equal, undivided interest in the net assets of the Trust attributable to the Units.

[5] The Manager is a Delaware corporation and is a wholly owned subsidiary of Apmex, Inc. (formerly known as American Precious Metals Exchange, Inc.). The Manager is responsible for the day-to-day activities and administration of the Trust. Additional details regarding the Trust are set forth in the Registration Statement for the Trust on Form F–1, filed with the Commission on December 23, 2011 (No. 333–178745) (as amended, ''Registration Statement'').

[6] RBC Dexia is affiliated with a broker-dealer. RBC Dexia has represented to NYSE Arca that it has put in place and will maintain the appropriate information barriers and controls between itself and the broker-dealer affiliate so that the broker-dealer affiliate will not have access to information concerning the composition and/or changes to the Trust's holdings that are not available on the Trust's Web site. *See* Notice, 77 FR at 17540, n.12.

[7] The Bank of Nova Scotia, a sub-custodian of RBC Dexia, will act as gold custodian for the 1 oz. gold coins that the Trust owns. *See id.*

[8] To purchase all of the 1 oz. gold coins, the Manager will negotiate on behalf of the Trust for multiple transactions with certain authorized distributors; all of the distributors are independent of the Manager and any affiliate of the parent company. *See* Notice, 77 FR at 17543. The Manager will not buy and sell 1 oz. gold coins for the Trust through its parent company or its affiliates. *See id.*

[9] *See* email from Tim Malinowski, Senior Director, NYSE Euronext, to Christopher W. Chow, Special Counsel, and Brian J. Baltz, Attorney-Advisor, Commission, dated April 26, 2012.

[10] With respect to application of Rule 10A–3 under the Act, the Trust relies on the exemption contained in Rule 10A–3(c)(7). *See* Notice, 77 FR at 17540, n.16.

[11] *See* Notice and the Registration Statement, *supra* notes 3 and 5, respectively.

[12] 15 U.S.C. 78f.

[13] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78f(b)(5).

on NYSE Arca is consistent with Section 11(a)(1)(C)(iii) of the Act,[15] which sets forth Congress's finding that it is in the public interest and appropriate for the protection of investors to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Quotation and last-sale information for the Units will be available via the Consolidated Tape Association. The Trust's Web site, which the Trust will launch upon the closing of the initial public offering, will provide an intraday indicative value (''IIV'') per share for the Units, as calculated by a third-party financial data provider during NYSE Arca's Core Trading Session (9:30 a.m. to 4 p.m. Eastern time).[16] In addition, the Trust's Web site will contain the following information, on a per-Unit basis, for the Trust: (a) The midpoint of the bid-ask price at the close of trading in relation to the NAV as of the time the NAV is calculated (''Bid/Ask Price''), and a calculation of the premium or discount of such price against such NAV; and (b) data in chart format displaying the frequency distribution of discounts and premiums of the Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. The Trust's Web site will also provide the Trust's prospectus, the two most recent reports to stockholders, the last sale price of the Units as traded in the U.S. market, and a breakdown of the holdings of the Trust by coin type. In addition, NYSE Arca will make available over the Consolidated Tape quotation information, trading volume, closing prices, and NAV for the Units from the previous day.

The Commission believes that the proposal to list and trade the Units is reasonably designed to promote fair disclosure of information that may be necessary to price the Units appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. As discussed above, the Trust will publish on its Web site: A breakdown of the holdings of the Trust by coin type, the NAV of the Trust, the IIV of the Shares, the Trust's prospectus, and the last sale price of the Units as traded in the U.S. market. The Commission notes that the Exchange will obtain a representation from the Trust prior to the commencement of trading of the Units that the NAV will be calculated daily and made available to all market participants at the same time.[17] Under NYSE Arca Equities Rule 7.34(a)(5), if the Exchange becomes aware that the NAV is not being disseminated to all market participants at the same time, it must halt trading on the NYSE Marketplace until such time as the NAV is available to all market participants. Additionally, if the IIV is not being disseminated as required, the Exchange may halt trading during the day in which the disruption occurs; if the interruption persists past the day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption.[18] Further, the Exchange will consider suspension of trading pursuant to NYSE Arca Rule 8.201(e)(2) if, after the initial 12-month period following commencement of trading: (1) The value of gold is no longer calculated or available on at least a 15-second delayed basis from a source unaffiliated with the Sponsor, Trust, or Custodian, or the Exchange stops providing a hyperlink on its Web site to any such unaffiliated commodity value; or (2) if the IIV is no longer made available on at least a 15-second delayed basis.[19] NYSE Arca will halt trading in the Units on the Exchange if trading in the Units is halted on TSX and in the event the Trust directs the Trust's Valuation Agent to suspend the calculation of the value of the net assets of the Trust and the NAV.[20] NYSE Arca Equities Rule 8.201(e)(2) also provides that NYSE Arca may seek to delist the Units in the event the value of the underlying commodity or the IIV is no longer calculated or available as required.

In support of this proposal, NYSE Arca has made representations, including:

(1) The Units will be subject to the initial and continued listing criteria under NYSE Arca Equities Rule 8.201.

(2) NYSE Arca's surveillance procedures are adequate to properly monitor Exchange trading of the Units in all trading sessions and to deter and detect violations of NYSE Arca rules and applicable federal securities laws.[21]

(3) Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Units. Specifically, the Information Bulletin will discuss the following: (a) The procedures for purchases and redemptions of Units; (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Units; (c) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Units prior to or concurrently with the confirmation of a transaction; (d) the possibility that trading spreads and the resulting premium or discount on the Units may widen as a result of reduced liquidity of gold trading during the Core and Late Trading Sessions after the close of the major world gold markets; and (e) trading information.

This approval order is based on the Exchange's representations.

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[22] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[23] that the

[15] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[16] The IIV will be calculated by (i) subtracting the closing spot price of gold for the prior business day from the current applicable spot price of gold (the ''Spread''); (ii) multiplying the Spread by the aggregate number of the Trust's 1 oz. gold coins for the prior business day (the ''Adjustment''); (iii) dividing the Adjustment by the aggregate number of units of the Trust outstanding for the prior business day (the ''Per-Unit Adjustment''); and (iv) adding the Per-Unit Adjustment to the NAV per Unit of the Trust for the prior business day.

[17] *See* email from Tim Malinowski, Senior Director, NYSE Euronext, to Christopher W. Chow, Special Counsel, and Brian J. Baltz, Attorney-Advisor, Commission, dated April 26, 2012.

[18] *See id.*

[19] More generally, NYSE Arca may halt trading on the Exchange in the Units because of market conditions or for reasons that, in the Exchange's view, make trading in the Units inadvisable, including: (1) The extent to which conditions in the underlying gold market have caused disruptions and/or lack of trading; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Additionally, trading in the Units will be subject to trading halts caused by extraordinary market volatility pursuant to NYSE Arca's ''circuit breaker'' rule. *See* NYSE Arca Equities Rule 7.12.

[20] *See* Notice, *supra* note 3, 77 FR at 17546.

[21] To support this, NYSE Arca states that, pursuant to NYSE Arca Equities Rule 8.201(g), it is able to obtain information regarding trading in the Units, physical gold, gold futures contracts, options on gold futures, or any other gold derivative from ETP Holders acting as registered Market Makers, in connection with their proprietary or customer trades. More generally, NYSE Arca states that it has regulatory jurisdiction over its ETP Holders and their associated persons, which includes any person or entity controlling an ETP Holder. With respect to a subsidiary or affiliate of an ETP Holder that does business only in commodities or futures contracts, the Exchange states that it could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations of which such subsidiary or affiliate is a member. Further, NYSE Arca states that it may obtain trading information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members of the ISG, including the COMEX. The Exchange also states that The Investment Industry Regulatory Organization of Canada is a member of ISG.

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78s(b)(2).

proposed rule change (SR–NYSEArca–2012–18) is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–11363 Filed 5–10–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66935; File No. SR–Phlx–2012–58]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the Pricing Schedule Regarding the Co-Location Super High Density Cabinet Monthly Fee

May 7, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 27, 2012, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify Phlx's Pricing Schedule at Section X(a), entitled ''Co-Location Services'' regarding the Exchange's co-location super high-density cabinet monthly fee. The Exchange will implement the proposed change on May 1, 2012.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXRulefilings*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify Phlx's Pricing Schedule at Section X(a) to reduce the co-location super high-density cabinet on-going monthly fee from $15,000 per month to $13,000 per month. The installation fee for the super high-density cabinet will remain the same.

Co-location customers have the option of obtaining several cabinet sizes and power densities. The co-located customer may obtain a half cabinet, a low density cabinet, a medium density cabinet, a medium-high density cabinet and a high density cabinet.[3] Each cabinet may vary in size and maximum power capacity. The fees related to the cabinet and power usage are incremental, with additional charges being imposed based on higher levels of cabinet and/or power usage, the use of non-standard cabinet sizes or special cabinet cooling equipment. The co-location customer may obtain more power by choosing a combination of lower power density cabinets.

The Exchange previously filed an immediately effective filing with the Commission to offer another choice of cabinet, specifically a larger cabinet (30″ W x 48″ D x 96″ H) with higher power (''Super High Density Cabinet'') as an alternative to combining several units for more power (>10kW<=17.3kW).[4] Currently, the installation fee for the Super High Density Cabinet is $7,000; and the on-going monthly fee is $15,000. At this time, the Exchange proposes to reduce the current on-going monthly fee to $13,000 to bring the fee in line with Exchange fees for similar power levels using multiple cabinets.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[5] in general, and with Section 6(b)(4) of the Act,[6] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls.

The Exchange believes the proposed reduction of the on-going monthly fee is reasonable because it is in line with Exchange fees for similar power levels using multiple cabinets. Also, the Exchange believes the reduction to the on-going monthly fee is equitable and not unfairly discriminatory because the super high-density power option is entirely voluntary and available to all members; therefore, the reduction is available to all members that select this power option. Also, the Exchange believes the reduction in fees is equitable and not unfairly discriminatory because the reduction diminishes the disparity in the Exchange's fees for various co-location power options. This results in a more competitive cost structure for the Exchange.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other trading venues. These competitive forces help to ensure that the Exchange's fees are reasonable, equitably allocated, and not unfairly discriminatory since market participants can largely avoid fees to which they object by changing their operating venue.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The Exchange is reducing fees through this proposed Pricing Schedule change, thereby enhancing the competitiveness of its co-location offering.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 7034(a).

[4] *See* Securities Exchange Act Release No. 66429 (February 21, 2012), 77 FR 11611 (February 27, 2012) (SR–Phlx–2012–20).

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[7] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–Phlx–2012–58 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–Phlx–2012–58. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–Phlx–2012–58 and should be submitted on or before June 1, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–11432 Filed 5–10–12; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b)(3)(A)(ii).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66937; File No. SR–NYSEArca–2012–05]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Adding New Paragraph (cc) to NYSE Arca Options Rule 6.62 To Provide for a Post No Preference Light Only Quotation

May 7, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on May 3, 2012, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to add new paragraph (cc) to NYSE Arca Options Rule 6.62 to provide for a Post No Preference Light Only Quotation (''PNPLO Quotation''). The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *www.nyse.com.*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to add new paragraph (cc) to NYSE Arca Options Rule 6.62 to provide for a PNPLO Quotation.

As described in proposed new paragraph (cc), a PNPLO Quotation would be an electronic Market Maker quotation that, upon initial entry into the NYSE Arca System, would only be eligible to execute against displayed liquidity on the Consolidated Book. In this regard, a PNPLO Quotation would be similar to the Post No Preference Light Order (''PNP-Light Order'') under NYSE Arca Options Rule 6.62(v), which is a non-routable order type that is only eligible to execute against displayed liquidity. Under the proposed rule, a PNPLO Quotation that, upon entry, would execute exclusively against non-displayed liquidity on the Consolidated Book will be immediately rejected by the NYSE Arca System. Additionally, a PNPLO Quotation that, upon entry, would execute against both displayed and non-displayed liquidity on the Consolidated Book will immediately execute only against the displayed liquidity, but not against the non-displayed liquidity, and any remaining size of the PNPLO Quotation will be immediately rejected by the NYSE Arca System. Furthermore, a PNPLO Quotation that, upon entry, would execute exclusively against displayed liquidity on the Consolidated Book will immediately execute against the displayed liquidity and any remaining size of the PNPLO Quotation will be placed on the Consolidated Book and treated like a standard Market Maker quotation.[3] Lastly, a PNPLO Quotation

[3] This would include being eligible to interact with non-displayed liquidity on the Consolidated Book.

that would not execute against either displayed or non-displayed liquidity will be placed in the Consolidated Book and treated as a standard Market Maker quotation.

The Exchange notes that the NYSE Arca System would automatically remove the pre-existing quotation(s) of a Market Maker upon entry of a PNPLO Quotation, as it does upon the entry of any other quotation, regardless of the acceptance or rejection of the PNPLO Quotation by the NYSE Arca System. Accordingly, in the event that a PNPLO Quotation is rejected by the NYSE Arca System, the Market Maker would be required to re-enter a quotation for purposes of satisfying any applicable quoting obligations under NYSE Arca Options Rule 6.37B.

The Exchange is proposing to offer this new quote type to provide Market Makers with greater control over the circumstances in which their quotations interact with contra-side trading interest on the Exchange by preventing interaction with non-displayed liquidity. This increase in control is desirable from the perspective of Market Makers because it is difficult for them to account for non-displayed liquidity in their quoting models. In addition, Market Makers on NYSE Arca in penny pilot issues receive post liquidity credits for electronic executions against their quotes that are resting in the Consolidated Book, and are charged take liquidity fees when their quotes execute against resting liquidity in the Consolidated Book. Market Makers consider these fees when calculating their quotes, and they may provide a wider quote than they otherwise would if they believe there is a chance that they would be charged a take liquidity fee for submitting a quote that executes against non-displayed liquidity (instead of receiving a post liquidity credit for executions against a resting quote). By eliminating the risk of incurring additional fees, the PNPLO Quotation may lead Markets Makers to provide narrower quotes on the Exchange, which in turn would benefit investors.

The Exchange further notes that the PNPLO Quotation would not be the only non-standard quote type at the Exchange. In this respect, the Exchange already offers a Price Improving Quote type, which allows a Market Maker to enter a quote that is better than the minimum price variation in an option and that is rounded for display purposes (up for offers and down for bids) so that it is displayed at the minimum price variation in the option.[4]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

Like the existing Price Improving Quote, the proposed PNPLO Quotation would provide a Market Maker with the ability to control its interactions with contra-side liquidity.[7] Specifically, upon initial entry, a PNPLO Quotation would not be eligible to interact with non-displayed liquidity. In this regard, the Exchange understands that a Market Maker's quoting algorithm can take into account existing liquidity in the marketplace, but may not be able to accurately account for the risk of interacting with non-displayed liquidity. As noted, Market Makers on NYSE Arca in penny pilot issues receive post liquidity credits for electronic executions against their quotes that are resting in the Consolidated Book, [sic] and are charged take liquidity fees when their quotes execute against resting liquidity in the Consolidated Book. Market Makers consider these fees when calculating their quotes, and they may provide a wider quote than they otherwise would if they believe there is a chance that they would be charged a take liquidity fee for submitting a quote that executes against non-displayed liquidity (instead of receiving a post liquidity credit for executions against a resting quote). Accordingly, the PNPLO Quotation would permit Market Makers to eliminate from their quoting decisions the risk of incurring certain fees, and therefore may result in narrower quote widths, which would increase the quality of the Exchange's market and thereby benefit investors.

The Exchange believes that the PNPLO Quotation is just, equitable and not unfairly discriminatory. For example, the PNPLO Quotation treats all similarly situated market participants the same in that it would be available for use by all Market Makers on the Exchange. Moreover, the Exchange notes that all market participants, including Market Makers, already have the ability to avoid trading with non-displayed liquidity by entering PNP–Light Orders, which have existed on the Exchange since 2009.[8] The Exchange also notes that market participants that enter non-displayed liquidity (*i.e.,* orders with reserve size) are choosing not to have the full size of their trading interest displayed, which is in contrast to the Commission's encouragement of a market structure in which trading interest is displayed,[9] and accordingly do not receive all of the benefits with respect to that non-displayed liquidity that are afforded to displayed liquidity.[10] For the forgoing reasons, the Exchange believes that the proposal is not unfairly discriminatory. Overall, the Exchange believes that the proposal protects investors and the public interest because it may contribute to more aggressive quoting by Market Makers and may lead to more displayed liquidity on the Exchange, which, in turn, should increase the quality of the Exchange's market and benefit investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

[4] *See* NYSE Arca Options Rule 6.62(s), which provides, in part, that a Price Improving Quote is a quote ''to buy or sell an option at a specified price at an increment smaller than the minimum price variation in the security,'' which ''may be entered in increments as small as one cent.''

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *See supra* note 5.

[8] The Exchange notes that it adopted the PNP–Light Order type pursuant to Section 19(b)(3)(A) of the Exchange Act, and that the rule filing adopting that order type was not abrogated. *See* Securities Exchange Act Release 59603 (March 19, 2009), 74 FR 13279 (March 26, 2009) (SR–NYSEArca–2009–21) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NYSE Arca, Inc. Amending Rule 6.62 to Provide Additional Order Types).

[9] *See, e.g.,* Securities Exchange Act Release No. 60684 (September 18, 2009), 74 FR 48632, 48636 (September 23, 2011) (File No. S7–21–09) (Proposed Elimination of Flash Order Exception from Rule 602 of Regulation NMS) (''The Commission long has emphasized the need to encourage displayed liquidity in the form of publicly displayed limit orders.'').

[10] In this regard, the Exchange notes that non-displayed liquidity is not afforded trade-through protection under Section 5 of the Options Order Protection and Locked/Crossed Market Plan. *See, e.g.,* Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362 (August 6, 2009) (File No. 4–546).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2012–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2012–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NYSEArca–2012–05 and should be submitted on or before June 1, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–11433 Filed 5–10–12; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66934; File No. SR–CBOE–2012–040]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Proposed Rule Change Related to Permanent Approval of Its Pilot on FLEX Minimum Value Sizes

May 7, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 25, 2012, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to make permanent its pilot program regarding minimum value sizes for Flexible Exchange Options (''FLEX Options'').[3] The text of the rule proposal is available on the Exchange's Web site (*http://www.cboe.org/legal*), at the Exchange's Office of the Secretary and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 28, 2010, the Exchange received approval of a rule change that, among other things, established a pilot program that eliminated minimum value sizes for FLEX Options. The pilot program is currently set to expire on the earlier of November 2, 2012 or the date on which the pilot program is approved on a permanent basis.[4] The purpose of this rule change filing is to make the pilot program permanent.

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[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] FLEX Options provide investors with the ability to customize basic option features including size, expiration date, exercise style, and certain exercise prices. FLEX Options can be FLEX Index Options or FLEX Equity Options. In addition, other products are permitted to be traded pursuant to the FLEX trading procedures. For example, credit options are eligible for trading as FLEX Options pursuant to the FLEX rules in Chapters XXIVA and XXIVB. *See* CBOE Rules 24A.1(e) and (f), 24A.4(b)(1) and (c)(1), 24B.1(f) and (g), 24B.4(b)(1) and (c)(1), and 28.17. The rules governing the trading of FLEX Options on the FLEX Request for Quote (''RFQ'') System platform are contained in Chapter XXIVA. The rules governing the trading of FLEX Options on the FLEX Hybrid Trading System platform are contained in Chapter XXIVB.

[4] At the same time the minimum value size pilot program was established, the Exchange also established a pilot program regarding permissible exercise settlement values for FLEX Index Options. Securities Exchange Act Release Nos. 61439 (January 28, 2010), 75 FR 5831 (February 4, 2010) (SR–CBOE–2009–087) (Approval Order); 61676 (March 9, 2010), 75 FR 13191 (March 18, 2010) (SR–CBOE–2010–026) (technical rule change to include original pilots' conclusion date of March 28, 2011 in the rule text); 64110 (March 24, 2011), 76 FR 17463 (March 29, 2011) (SR–CBOE–2011–024) (extending the pilots through March 30, 2012); and 66701 (March 30, 2012), 77 FR 20673 (April 5, 2012) (SR–CBOE–2012–027) (extending the pilots through the earlier of November 2, 2012 or the date on which the respective pilot program is approved on a permanent basis). The Exchange is not currently proposing permanent approval of the exercise settlement values pilot program for FLEX Index Options. Any such proposal would be the subject of a separate rule change filing.

Background on the Pilot

Prior to the initiation of the minimum value size pilot, the minimum value size requirements under CBOE Rules 24A.4 and 24B.4 were as follows:

- For opening transactions in any FLEX series in which there is no open interest at the time a FLEX RFQ or FLEX Order, as applicable, is submitted, the minimum value size was (i) for FLEX Equity Options, the lesser of 250 contracts or the number of contracts overlying $1 million in the underlying securities; and (ii) for FLEX Index Options, $10 million Underlying Equivalent Value. Under a prior pilot program (which was superseded by the minimum value size pilot program), the ''250 contracts'' component above had been reduced to ''150 contracts.''[5]
- For a transaction in any currently-opened FLEX series resulting from an RFQ or from trading against the electronic book (other than FLEX Quotes responsive to a FLEX Request for Quotes and FLEX Orders submitted to rest in the electronic book), the minimum value size was (i) for FLEX Equity Options, the lesser of 100 contracts or the number of contracts overlying $1 million in the underlying securities in the case of opening transactions, and 25 contracts in the case of closing transactions; and (ii) for FLEX Index Options, $1 million Underlying Equivalent Value in the case of both opening and closing transactions; or (iii) in either case the remaining underlying size or Underlying Equivalent Value on a closing transaction, whichever is less.
- The minimum value size for FLEX Quotes responsive to an RFQ and FLEX Orders (undecremented size) submitted to rest in the electronic book was 25 contracts in the case of FLEX Equity Options, and $1 million Underlying Equivalent Value in the case of FLEX Index Options, or in either case the remaining underlying size or Underlying Equivalent Value on a closing transaction, whichever is less. In addition, with respect to FLEX Index Appointed Market-Makers, FLEX Quotes and FLEX Orders (undecremented size) must have been for at least $10 million Underlying Equivalent Value or the dollar amount indicated in the Request for Quote (if applicable), whichever is less.

Under the minimum value size pilot, these minimum value size requirements were eliminated.[6] As mentioned above, the minimum value size pilot is currently set to expire on the earlier of November 2, 2012 or the date on which the pilot program is approved on a permanent basis.

Proposal

CBOE is proposing to make the minimum value size pilot program permanent. CBOE believes the pilot program has been successful and well received by its membership and the investing public for the period that it has been in operation as a pilot.

To accomplish this change, CBOE is proposing to eliminate the rule text describing the pilot program, which descriptions are contained in CBOE Rules 24A.4.01, FLEX Pilot Programs, and 24B.4.01, FLEX Pilot Programs; and to eliminate the rule text describing the minimum value size requirements, which descriptions are contained in CBOE Rules 24A.4(a)(4) and 24B.4(a)(5) and cross-referenced in paragraph (b) of CBOE Rule 24A.9, FLEX Market-Maker Appointments and Obligations, and paragraph (c) of CBOE 24B.9, FLEX Market-Maker Appointments and Obligations.

In conjunction with these changes, the Exchange is proposing certain non-substantive changes to reorganize the rule text. In particular, text from CBOE Rules 24A.4(a)(4)(i) and 24B.4(a)(5)(i) pertaining to the maximum fifteen (15) year term for a FLEX Option is proposed to be relocated and combined with the text of CBOE Rules 24A.4(a)(2)(iv) and 24B.4(a)(2)(iv), respectively, which describe FLEX Option expiration date requirements. As modified, Rules 24A.4(a)(2)(iv) and 24B.4(a)(2)(iv) will state that the expiration date may be any business day specified as to day, month, and year, not to exceed a maximum of fifteen (15) years, except that a FLEX Index Option that expires on any business day that falls on, or within two business days of, a third Friday-of-the-month expiration day for any Non-FLEX Option other than a QIX option) (''Expiration Friday''), may only have an exercise settlement value on the expiration date determined by reference to the reported level of the index as derived from the opening prices of the component securities (''a.m. settlement'').[7] Finally, the minimum percentage requirements for FLEX Appointed Market-Maker responses to electronic Request for Quotes set forth in CBOE Rule 24B.4(a)(5)(iv) will be relocated to CBOE Rule 24B.9(c) (and replace an existing cross-reference in Rule 24B.9(c) to Rule 24B.4(a)(5)(iv)). These changes are proposed simply to reorganize the rule text in light of the other changes being proposed. As noted above, the changes are not substantive.

In support of approving the pilot program on a permanent basis, and as required by the pilot program's approval order, the Exchange has submitted to the Commission a pilot program report regarding the pilot, which details the Exchange's experience with the program. Specifically, the Exchange provided the Commission an annual report containing data and analysis of underlying equivalent values, open interest and trading volume, and analysis of the types of investors that initiated opening FLEX Equity and Index Options transactions (i.e., institutional, high net worth, or retail). The report was provided to the Commission on a confidential basis.

The Exchange believes there is sufficient investor interest and demand in the pilot program to warrant its permanent approval. The Exchange believes that, for the period that the pilot has been in operation, the program has provided investors with additional means of managing their risk exposures and carrying out their investment objectives. Furthermore, as discussed in more detail below, the Exchange has not experienced any adverse market effects with respect to the pilot program.

CBOE believes that eliminating the minimum value size requirements for all FLEX Options on a permanent basis is important and necessary to the Exchange's efforts to create a product and market that provides its membership and investors interested in FLEX-type options with an improved but comparable alternative to the over-the-counter (''OTC'') market in customized options, which can take on contract characteristics similar to FLEX Options but are not subject to the same restrictions. By making the pilot permanent, market participants will continue to have greater flexibility in determining whether to execute their customized options in an exchange environment or in the OTC market. CBOE believes market participants

[5] *See* Securities Exchange Act Release No. 57249 [sic] (March 4, 2008), 73 FR 13058 (March 11, 2008) (SR–CBOE–2006–36) (approval of rule change that, among other things, established a pilot program that reduced the minimum number contracts required for a FLEX Equity Option opening transaction in an new series).

[6] The provisions in CBOE Rules 24A.9(b) and 24B.9(c) that provide that every FLEX Quote entered by a FLEX Appointed Market-Maker or a FLEX Qualified Market-Maker shall meet or exceed the minimum value size parameters set forth in CBOE Rules 24A.4(a)(4)(iv) and 24B.4(a)(5)(iv), respectively, have not been/are not applicable during the duration of the pilot program. This is because all minimum value size requirements under CBOE Rules 24A.4(a)(4) and 24B.4(a)(5) have been eliminated under the pilot program.

[7] The Exchange notes that the a.m. settlement limitation on permissible exercise settlement values for FLEX Index Options with an Expiration Friday expiration has been eliminated on a pilot basis. *See* CBOE Rules 24A.4.01 and 24B.4.01 and note 4, *supra*.

benefit from being able to trade these customized options in an exchange environment in several ways, including, but not limited to the following: (i) Enhanced efficiency in initiating and closing out positions; (ii) increased market transparency; and (iii) heightened contra-party creditworthiness due to the role of The Options Clearing Corporation (''OCC'') as issuer and guarantor of FLEX Options. The Exchange also believes the pilot programs are wholly consistent with comments by Timothy F. Geithner, Secretary of the Treasury, to the U.S. Senate. In particular, Secretary Geithner has stated that:

> Market efficiency and price transparency should be improved in derivatives markets by requiring the clearing of standardized contracts through regulated [central counterparties] and by moving the standardized part of these markets onto regulated exchanges and regulated transparent electronic trade execution systems for OTC derivatives and by requiring development of a system for timely reporting of trades and prompt dissemination of prices and other trade information. Furthermore, regulated financial institutions should be encouraged to make greater use of regulated exchange-traded derivatives. Competition between appropriately regulated OTC derivatives markets and regulated exchanges will make both sets of markets more efficient and thereby better serve end-users of derivatives.[8]

The Exchange believes that the elimination of the minimum value size requirements on a permanent basis would provide FLEX-participating Trading Permit Holders with greater flexibility in structuring the terms of FLEX Options that best comports with their and their customers' particular needs. In this regard, the Exchange notes that the minimum value size requirements were originally put in place over nineteen years ago to limit participation in FLEX Options to sophisticated, high net worth investors rather than retail investors.[9] However, the Exchange believes the restriction is no longer necessary and is overly restrictive. The Exchange has also not experienced any adverse market effects with respect to the pilot program eliminating the minimum value size requirements. Again, based on the Exchange's experience to date and over the pilot period, the minimum value size requirements are too large to accommodate the needs of Trading Permit Holders and their customers—who may be institutional, high net worth or retail—that currently participate in the OTC market. In this regard, the Exchange notes that, prior to establishing the minimum value size pilot, it received numerous requests from broker-dealers representing institutional, high net worth and retail investors indicating that the minimum value size requirements prevented them from bringing transactions that are already taking place in the OTC market to an exchange environment. The Exchange believes that eliminating the minimum value size requirements on a permanent basis would further broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where similar size restrictions do not apply. The Exchange also believes that this may open up FLEX Options to more retail investors. The Exchange does not believe this raises any unique regulatory concerns because existing safeguards—such as certain position limit, aggregation and exercise limit requirements, reporting requirements, and margin requirements—continue to apply.[10] In addition, the Exchange notes that FLEX Options are subject to the options disclosure document (''ODD'') requirements of Rule 9b–1 [11] under the Act.[12] No broker or dealer can accept an order from a customer to purchase or sell an option contract relating to an options class that is the subject of a definitive ODD (including FLEX Options), or approve the customer's account for the trading of such an option, unless the broker or dealer furnishes or has furnished to the customer a copy of the definitive ODD. The ODD contains a description, special features, and special risks of FLEX Options. Lastly, similar to any other options, FLEX Options are subject to Trading Permit Holder organization supervision and suitability requirements, such as in CBOE Rules 9.8, *Supervision of Accounts,* and 9.9, *Suitability of Recommendations.*

In proposing the pilot itself and in now proposing to make it permanent, CBOE is cognizant of the need for market participants to have substantial options transaction capacity and flexibility to hedge their substantial investment portfolios, on the one hand, and the potential for adverse effects that the minimum value size restrictions were originally designed to address, on the other. However, the Exchange has not experienced any adverse market effects with respect to the pilot program. CBOE is also cognizant of the OTC market, in which similar restrictions on minimum value size do not apply. In light of these considerations and Secretary Geithner's comments on moving the standardized parts of OTC contracts onto regulated exchanges, CBOE believes that making the pilot permanent is appropriate and reasonable and will provide market participants with additional flexibility in determining whether to execute their customized options in an exchange environment or in the OTC market. CBOE believes market participants benefit from being able to trade these customized options in an exchange environment in several ways, including, but not limited to, enhanced efficiency in initiating and closing out positions, increased market transparency, and heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of FLEX Options.

For the foregoing reasons, CBOE believes that the minimum value size pilot program is reasonable and appropriate, promotes just and equitable principles of trade, and facilitates transactions in securities while continuing to foster the public interest and investor protection, and therefore should be made permanent.

[8] *See* letter from Secretary Geithner to the Honorable Harry Reid, United States Senate (May 13, 2009), located at *http://www.financialstability.gov/docs/OTCletter.pdf.*

[9] *See* Securities Exchange Act Release Nos. 31361 (October 27, 1992) 57 FR 52655 (November 4, 1992) (SR–CBOE–92–17)(notice of filing of proposed rule change relating to Flexible Exchange Options) and 31920 (February 24, 1993), 58 FR 12280 (March 3, 1993) (order approving SR–CBOE–92–17).

[10] The Exchange also notes that certain position limit, aggregation and exercise limit requirements continue to apply to FLEX Options in accordance with CBOE Rules 24A.7, *Position Limits and Reporting Requirements,* 24A.8, *Exercise Limits,* 24B.7, *Position Limits and Reporting Requirements,* and 24B.8, *Exercise Limits.* Additionally, all FLEX options remain subject to the position reporting requirements in paragraph (a) of CBOE Rule 4.13, *Reports Related to Position Limits.* CBOE Rule 4.13(a) provides that ''[i]n a manner and form prescribed by the Exchange, each Trading Permit Holder shall report to the Exchange, the name, address, and social security or tax identification number of any customer who, acting alone, or in concert with others, on the previous business day maintained aggregate long or short positions on the same side of the market of 200 or more contracts of any single class of option contracts dealt in on the Exchange. The report shall indicate for each such class of options, the number of option contracts comprising each such position and, in the case of short positions, whether covered or uncovered.'' For purposes of this Rule, the term ''customer'' in respect of any Trading Permit Holder includes ''the Trading Permit Holder, any general or special partner of the Trading Permit Holder, any officer or director of the Trading Permit Holder, or any participant, as such, in any joint, group or syndicate account with the Trading Permit Holder or with any partner, officer or director thereof.'' CBOE Rule 4.13(d). Moreover, the Exchange and its Trading Permit Holder organizations each have the authority, pursuant to CBOE Rule 12.10, *Margin Required is Minimum,* to impose additional margin as deemed advisable.

[11] 17 CFR 240.9b–1.

[12] 15 U.S.C. 78a *et seq.*

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act [13] in general and furthers the objectives of Section 6(b)(5) of the Act [14] in particular in that it should promote just and equitable principles of trade, serve to remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. Specifically, the Exchange believes that the permanent approval of the pilot program, which eliminates minimum value size requirements, would provide greater opportunities for investors to manage risk through the use of FLEX Options. Further, the Exchange notes that it has not experienced any adverse effects from the operation of the pilot program. The Exchange also believes that making the minimum value size pilot permanent does not raise any unique regulatory concerns. The Exchange also believes that the proposed rule change would continue to provide Trading Permit Holders and investors with additional opportunities to trade customized options in an exchange environment and subject to exchange-based rules, and investors would benefit as a result.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2012–040 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number *SR–CBOE–2012–040.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number *SR–CBOE–2012–040* and should be submitted on or before June 1, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–11365 Filed 5–10–12; 8:45 am]

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[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66936; File No. SR–ICEEU–2012–06]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change to Membership Qualifications for CDS Clearing Members That Are Us CDS Clearing Members

May 7, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2012, ICE Clear Europe Limited (''ICEEU'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared primarily by ICEEU. The Commission is publishing this Notice and Order to solicit comments on the proposed rule change from interested persons and to approve the proposed rule change on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

ICEEU proposes to conform the ICEEU membership qualifications with Commodity Futures Trading Commission (''CFTC'') Regulations 39.12(a)(2)(ii) and 39.12(a)(2)(iii) no later than the May 7, 2012, effective date of CFTC Regulations 39.12(a)(2)(ii) and 39.12(a)(2)(iii).

As discussed in more detail in Item II(A) below, the changes to Parts 1 and 2 of the ICEEU CDS Procedures provide for amendments to the membership qualifications for US credit default swap (''CDS'') clearing members.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICEEU included statements concerning the purpose of and basis for the proposed rule change and discussed any

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. ICEEU has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

ICEEU is registered as a derivatives clearing organization (''DCO'') with the CFTC and clears CDS contracts subject to the jurisdiction of the CFTC. CFTC Regulation 39.12(a)(2)(ii) provides that ''the participant requirements shall set forth capital requirements that are based on objective, transparent, and commonly accepted standards that appropriately match capital to risk. Capital requirements shall be scalable to the risks posed by clearing members.'' Accordingly, ICEEU proposes to revise its CDS Procedures 2.6 to provide that, if at any time and for so long as a CDS Clearing Member that is an FCM has a required contribution to the ICEEU CDS guaranty fund that exceeds 25% of its ''excess net capital'', ICEEU may (in addition to other rights) require such US CDS Clearing Member to provide additional margin and/or prepay and maintain with ICEEU an amount up to the US CDS Clearing Member's CDS guaranty fund assessment obligation. ICEEU CDS Procedures 1.1 (Additional Definitions), the definitional section of ICEEU's Rules, would be amended to define ''excess net capital'' as the amount reported on Form 1–FR–FCM or FOCUS Report or as otherwise reported to the CFTC under CFTC Rule 1.12 (or an equivalent amount for US CDS Clearing Members that are not futures commission merchants).

CFTC Regulation 39.12(a)(2)(iii) provides that ''a derivatives clearing organization shall not set a minimum capital requirement of more than $50 million for any person that seeks to become a clearing member in order to clear swaps.'' Accordingly, ICEEU proposes to revise CDS Procedure 2.2(b) to incorporate the CFTC mandated $50 million minimum adjusted net capital requirement for US CDS clearing members. ICEEU proposes to define the term ''US CDS Clearing Member'' to mean ''a CDS Clearing Member or applicant that would become a CDS Clearing Member that is (i) an FCM or (ii) any other Person organised or incorporated under the laws of the United States of America or a state thereof.'' ICEEU also proposes to amend CDS Procedure 2.2(b)(ii) and (iii) to eliminate references to external credit ratings as part of the membership qualifications for US CDS Clearing Members. In addition, CDS Procedure 2.2(b)(iv) would be added which states one additional membership qualification for US CDS clearing members. It requires that the US CDS Clearing Member be regulated ''for capital adequacy (the ''Regulatory Capital Requirement'') by a competent authority such as the FSA, CFTC, SEC, Banque de France, Bundesbank, Bundesanstalt für Finanzdienstleistungsaufsicht, Swiss Federal Banking Commission, U.S. Federal Reserve Board, U.S. Office of the Comptroller of the Currency, or any other Regulatory Authority the Clearing House designates from time to time for this purpose, or it is an Affiliate of an entity that satisfies the Regulatory Capital Requirement and is subject to consolidated holding company group supervision.''

Further, CDS Procedure 2.7 would be added to clarify that a ''US CDS Clearing Member that is not an FCM Clearing Member shall provide to the Clearing House a copy of such forms as the Clearing House may determine to be necessary on a comparable schedule to that which an FCM Clearing Member would be required to follow in filing such forms with its Regulatory Authorities.''

ICEEU argues that the proposed rule changes are consistent with the requirements of Section 17A of the Act and the regulations thereunder applicable to it and that the proposed membership requirements will comply with the Act and the rules and regulations thereunder.

(B) Self-Regulatory Organization's Statement on Burden on Competition

ICEEU does not believe the proposed rule change would have any impact, or impose any burden, on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICEEU represented that it will notify the Commission of any written comments it receives.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

- Electronic comments may be submitted by using the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or by sending an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2012–06 on the subject line.
- Paper comments may be sent in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2012–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICEEU and on ICEEU's Web site at *https://www.theice.com/notices/Notices.shtml?regulatoryFilings.*

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2012–06 and should be submitted on or before June 1, 2012.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

Section 19(b)(2)(C) of the Act[4] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the

[3] The Commission has modified the text of the summaries prepared by ICEEU.

[4] 15 U.S.C. 78s(b)(2)(C).

rules and regulations thereunder applicable to such organization. Section 17A(b)(3)(F) of the Act [5] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to the extent applicable, derivative agreements, contracts, and transactions.

The proposed change would allow ICEEU to expand the base of potential clearing members by lowering the net capital threshold for membership, thereby promoting the prompt and accurate clearance and settlement of securities transactions, and derivative agreements, contracts, and transactions. It would also allow ICEEU to comply with new CFTC regulatory requirements, thereby promoting the prompt and accurate clearance and settlement of derivative agreements, contracts, and transactions.

Further, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[6] for approving the proposed rule change prior to the 30th day after the date of publication of notice in the **Federal Register** because, as a registered DCO, ICEEU is required to comply with the new CFTC regulations by the time they become effective on May 7, 2012.[7]

V. Conclusion

It is therefore ordered, pursuant to 19(b)(2) of the Act,[8] that the proposed rule change (SR–ICEEU–2012–06) is approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–11368 Filed 5–10–12; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 15 U.S.C. 78s(b)(2).

[7] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66931; File No. SR–CME–2012–15]

Self-Regulatory Organizations; Chicago Mercantile Exchange Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Adoption of Interest Rate Futures Contracts Portfolio Margining Program With Eris Exchange, LLC

May 7, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on April 25, 2012, Chicago Mercantile Exchange Inc. (''CME'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II and III below, which Items have been prepared substantially by CME. CME filed the proposal pursuant to Section 19(b)(3)(A) of the Act, and Rule 19b–4(f)(4)(ii) [2] thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CME proposes to adopt an interest rate futures contracts portfolio margining program with Eris Exchange, LLC (''Eris''). CME currently clears interest rate swap futures contracts listed by Eris. Separately, the CME clearinghouse settles and clears Eurodollar futures listed by CME. CME is proposing to adopt a program that would allow it to offer portfolio margining of CME Eurodollar futures together with Eris Exchange Interest Rate Swap futures. The portfolio margining program will allow accounts with offsetting positions in CME Eurodollar futures and Eris Exchange contracts to obtain risk offsets and, hence, lower performance bond (*i.e.,* initial margin) requirements. The proposed change will immediately become effective on filing but will not become operational until April 30, 2012.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CME included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. CME has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

CME currently clears interest rate swap futures contracts listed by Eris. Separately, the CME clearinghouse settles and clears Eurodollar futures listed by CME. CME is proposing to adopt a program that would allow it to offer portfolio margining of CME Eurodollar futures together with Eris Exchange Interest Rate Swap futures. The proposed rule change will immediately become effective on filing but will not become operational until April 30, 2012.

The portfolio margining program will allow accounts with offsetting positions in CME Eurodollar futures and Eris Exchange contracts to obtain risk offsets and, hence, lower performance bond (i.e., initial margin) requirements. Actual risk offsets will vary by portfolio, and will be higher for more highly correlated positions. The reduced margin requirements will be reflected in datafiles provided by CME Clearing to clearing members. Firms will also be able to use CME's margin software to verify margin calculations for these portfolios and perform ''what if'' analyses.

The portfolio margining program would be available for house accounts and customer accounts. With regard to customer accounts, all products in the proposed program are futures governed by Section 4d(a)(2) of the Commodity Exchange Act and CFTC Regulations promulgated thereunder. CME notes that the proposed portfolio margining program comports with the CFTC's DCO Core Principle G (Risk Management), and with new CFTC Regulation 39.13(g)(4) (Spread and Portfolio Margins), which provides, in pertinent part, that a DCO ''may allow reductions in initial margin requirements for related positions if the price risks with respect to such positions are significantly and reliably correlated.''

CME also certified the proposed changes that are the subject of this filing to its primary regulator, the CFTC, in CME Submission 12–114.

The proposed change is limited to CME's activities as a derivatives clearing organization clearing futures

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4(f)(4)(ii).

transactions. As such, the proposed change does not significantly affect the security-based swap clearing operations of CME or any related rights or obligations of CME security-based swap clearing participants. The proposed change is therefore properly filed under Section 19(b)(3)(A) and Rule 19b–4(f)(4)(ii) thereunder because it effects a change in an existing service of a registered clearing agency that primarily affects the futures clearing operations of the clearing agency with respect to futures that are not security futures and does not significantly affect any securities clearing operations of the clearing agency or any related rights or obligations of the clearing agency or persons using such service.

(B) Self-Regulatory Organization's Statement on Burden on Competition

CME does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

CME has not solicited, and does not intend to solicit, comments regarding this proposed change. CME has not received any unsolicited written comments from interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A) [3] of the Act and Rule 19b–4(f)(4)(ii) [4] thereunder because it effects a change in an existing service of CME that primarily affects the futures clearing operations of CME with respect to futures that are not security futures and does not significantly affect any securities clearing operations of CME or any related rights or obligations of the clearing agency or persons using such service. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CME–2012–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CME–2012–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of CME and on CME's Web site at *http://www.cmegroup.com*.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CME–2012–15 and should be submitted on or before June 1, 2012.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[5]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–11364 Filed 5–10–12; 8:45 am]

BILLING CODE 8011–01–P

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4)(ii).

[5] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before June 11, 2012. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer*, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030.

SUPPLEMENTARY INFORMATION:

Title: ''Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Tech-Net Database''.

Frequency: On occasion.

SBA Form Number: N/A.

Description of Respondents: Individuals, and small businesses, that are participating in the SBIR and STTR programs.

Responses: 13,500.

Annual Burden: 27,000.

Curtis Rich,

Acting Chief, Administrative Information Branch.

[FR Doc. 2012–11464 Filed 5–10–12; 8:45 am]

BILLING CODE P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes one new information collection, one extension of an OMB-approved information collection, and several revisions to existing information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, DCRDP, Attn: Reports Clearance Director, 107 Altmeyer Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OPLM.RCO@ssa.gov*.

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than July 10, 2012. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. *Automated Scheduling Application (ASA)—20 CFR 404.929, 404.936, 404.950, 416.1429, 416.1436, and 416.1450–416.1451—0960—NEW.* SSA is creating an online-based scheduling tool, the Automated Scheduling Application (ASA), to document the availability and special needs of participants for hearings before administrative law judges (ALJ). The respondents are disability applicants or recipients, ALJ staff, SSA Hearing Office employees, appointed representatives, medical experts, vocational experts, and verbatim hearing recorders who need to schedule or request special needs related to an ALJ hearing. All respondents will use the ASA system (via SSA's Intranet for SSA employees, and a public-facing Internet site for members of the public) to document their hearings availability and needs, and to view scheduled hearings in an electronic calendar. SSA staff will provide technical support to external users via our 800 number.

Type of Request: This is a new information collection request.

Respondent type	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)
Medical Experts, Vocational Experts & Hearing Reporters—Availability reported using the external ASA	3,300	52	171,600	8	22,880
Appointed Representatives—Availability reported using the external ASA	16,600	52	863,200	8	115,093
Medical Experts, Vocational Experts & Hearing Reporters—requests to HO to change availability using internal ASA	3,300	6	19,800	8	2,640
Appointed Representatives—requests to HO to change availability using internal ASA	16,600	6	99,600	8	13,280
Totals	39,800		1,154,200		153,893

2. *Statement of Claimant or Other Person—20 CFR 404.702 & 416.570—0960–0045.* In cases where claimants or others want to share information relating to Supplemental Security Income (SSI) or Social Security benefits, and SSA has no standard form to document this information, the agency uses form SSA–795. The agency documents whatever information the claimant or other member of the public provides, and considers it when processing benefits claims or when making decisions on ongoing issues relating to the above programs. The respondents are applicants or recipients of SSI or Social Security benefits, or others who are in a position to provide relevant information on an existing claim or case.

Type of Request: Revision of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–795	305,500	1	15	76,375

3. *Authorization for the Social Security Administration to Obtain Account Records from a Financial Institution and Request for Records (Medicare)—0960–0729.* Under the aegis of the Medicare Modernization Act of 2003, Medicare beneficiaries can apply for a Medicare Prescription Drug Plan (Part D) program subsidy. In some cases, SSA will verify the details of applicants' accounts at financial institutions to determine if they are eligible for the

subsidy. Form SSA–4640 provides the applicant authorization SSA needs to contact financial institutions about applicants' accounts. Financial institutions use the form to verify the information SSA requests. The respondents are applicants for the Medicare Part D program subsidy, and the financial institutions where these applicants are account holders.

Type of Request: Revision of an OMB-approved information collection.

Type of respondent	Number of respondents	Frequency of Response	Average burden per response (minutes)	Estimated total annual burden (hours)
Medicare Part D Subsidy Applicants	5,000	1	1	83
Financial Institutions	5,000	1	4	333
Totals	10,000			416

4. *Statement of Reclamation Action—31 CFR Part 210—0960–0734.*

Regulations governing the Federal Government Participation in the Automated Clearing House (1) allow SSA to send Social Security payments to Canada and (2) mandate the reclamation of funds paid erroneously to a Canadian bank or financial institution after the death of a Social Security beneficiary. SSA uses Form SSA–1713, Notice of Reclamation Action, to collect information to determine if, how, and when the Canadian bank or financial institution is going to return erroneous payments after the death of a Social Security beneficiary who elected to have payments sent to Canada. Form SSA–1712 (or SSA–1712 CN), Notice of Reclamation-Canada Payment Made in the United States, is the cover sheet SSA prepares to request return of the payment. The respondents are Canadian banks and financial institutions who erroneously received Social Security payments.

Type of Request: Revision of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1713	15	1	5	1

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them within 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than June 11, 2012. Individuals can obtain copies of the OMB clearance packages by writing to *OPLM.RCO@ssa.gov.*

1. *Request for Reconsideration—Disability Cessation—20 CFR 404.909, 416.1409—0960–0349.* SSA uses Form SSA–789–U4 to arrange for a hearing or to prepare a decision based on the evidence of record. Specifically, claimants or their representatives use Form SSA–789–U4 to (1) ask SSA to reconsider a determination; (2) indicate if they wish to appear at a disability hearing; (3) submit any additional information or evidence for use in the reconsidered determination; and (4) indicate if they will need an interpreter for the hearing. The respondents are applicants or claimants for Social Security benefits or SSI payments.

Type of Request: Revision of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–789–U4	30,000	1	13	6,500

2. *Prohibition of Payment of SSI Benefits to Fugitive Felons and Parole/Probation Violators—20 CFR 416.708(o)—0960–0617.* Section 1611(e)(4) of the Social Security Act precludes eligibility for SSI payments for certain fugitives and probation/parole violators. Regulations at 20 CFR 416.708(o) require individuals applying for or receiving SSI benefits to report to SSA that (1) they are fleeing to avoid prosecution for a crime; (2) they are fleeing to avoid custody or confinement after conviction of a crime; or (3) they are violating a condition of probation or parole. SSA uses the information we receive to deny eligibility, or to suspend recipients' SSI payments. The respondents are SSI applicants and recipients, or representative payees of SSI applicants and recipients, who are reporting their status as a fugitive felons or probation/parole violators.

Type of Request: Extension of an OMB-approved information collection.

Collection instrument	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Modernized SSI Claims System Screens	1,000	1	1	17

Dated: May 7, 2012.

Naomi Sipple,

Reports Clearance Analyst, Office of Regulations and Reports Clearance, Social Security Administration.

[FR Doc. 2012–11328 Filed 5–10–12; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 7878]

List of Participating Countries and Entities Under the Clean Diamond Trade Act of 2003

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Department of State is identifying all the Participating Countries and Entities eligible for trade in rough diamonds under the Clean Diamond Trade Act of 2003, and their respective Importing and Exporting Authorities, and revising the previously published list of December 31, 2008 to add Swaziland.

FOR FURTHER INFORMATION CONTACT: Brad Brooks-Rubin, Special Advisor for Conflict Diamonds, Bureau of Economic, Energy, and Business Affairs, Department of State (202) 647–2856.

SUPPLEMENTARY INFORMATION: In accordance with Sections 3 and 6 of the Clean Diamond Trade Act of 2003 (Pub. L. 108–19) and Section 2 of Executive Order 13312 of July 29, 2003 the Department of State is identifying all the Participating Countries and Entities (Hereinafter Known as ''Participants'') eligible for trade in rough diamonds under the Clean Diamond Trade Act of 2003, and their respective Importing and Exporting Authorities, and revising the previously published list of December 31, 2008 (73 FR 80506) to add Swaziland.

Section 4 of the Clean Diamond Trade Act (the ''Act'') requires the President to prohibit the importation into, or the exportation from, the United States of any rough diamond, from whatever source, that has not been controlled through the Kimberley Process Certification Scheme (KPCS). Under Section 3(2) of the Act, ''controlled through the Kimberley Process Certification Scheme'' means an importation from the territory of a Participant or exportation to the territory of a Participant of rough diamonds that is either carried out in accordance with the KPCS, as set forth in regulations promulgated by the President, or controlled under a system determined by the President to meet substantially the standards, practices, and procedures of the KPCS. The referenced regulations are contained at 31 CFR part 592 (''Rough Diamonds Control Regulations''). Section 6(b) of the Act requires the President to publish in the **Federal Register** a list of all Participants, and all Importing and Exporting Authorities of Participants, and to update the list as necessary. Section 2 of Executive Order 13312 delegates this function to the Secretary of State. Section 3(7) of the Act defines ''Participant'' as a state, customs territory, or regional economic integration organization identified by the Secretary of State. Section 3(3) of the Act defines ''Exporting Authority'' as one or more entities designated by a Participant from whose territory a shipment of rough diamonds is being exported as having the authority to validate a Kimberley Process Certificate. Section 3(4) of the Act defines ''Importing Authority'' as one or more entities designated by a Participant into whose territory a shipment of rough diamonds is imported as having the authority to enforce the laws and regulations of the Participant regarding imports, including the verification of the Kimberley Process Certificate accompanying the shipment.

List of Participants

Pursuant to Section 3 of the Act, Section 2 of Executive Order 13312, and Delegation of Authority No. 245–1 (February 13, 2009), I hereby identify the following entities as of May 26, 2011, as Participants under section 6(b) of the Act. Included in this List are the Importing and Exporting Authorities for Participants, as required by Section 6(b) of the Act. This list revises the previously published list of December 31, 2008, to add Swaziland to the list of Participants in the Kimberley Process Certification Scheme.

Angola—Ministry of Geology and Mines.
Armenia—Ministry of Trade and Economic Development.
Australia—Exporting Authority—Department of Industry, Tourism and Resources; Importing Authority—Australian Customs Service.
Bangladesh—Ministry of Commerce.
Belarus—Department of Finance.
Botswana—Ministry of Minerals, Energy and Water Resources.
Brazil—Ministry of Mines and Energy.
Canada—Natural Resources Canada.
Central African Republic—Ministry of Energy and Mining.
China—General Administration of Quality Supervision, Inspection and Quarantine.
Democratic Republic of the Congo—Ministry of Mines.
Republic of Congo—Ministry of Mines.
Croatia—Ministry of Economy.
European Union—DG/External Relations/A.2.
Ghana—Precious Minerals and Marketing Company Ltd.
Guinea—Ministry of Mines and Geology.
Guyana—Geology and Mines Commission.
India—The Gem and Jewelry Export Promotion Council.
Indonesia—Directorate General of Foreign Trade of the Ministry of Trade.
Israel—The Diamond Controller.
Japan—Ministry of Economy, Trade and Industry.
Republic of Korea—Ministry of Commerce, Industry and Energy.
Laos—Ministry of Finance.
Lebanon—Ministry of Economy and Trade.
Lesotho—Commissioner of Mines and Geology.
Liberia—Ministry of Lands, Mines and Energy.
Malaysia—Ministry of International Trade and Industry.
Mauritius—Ministry of Commerce.
Namibia—Ministry of Mines and Energy.
Mexico—Economic Secretariat.
New Zealand—Ministry of Foreign Affairs and Trade.
Norway—The Norwegian Goldsmiths' Association.
Russia—Gokhran, Ministry of Finance.
Sierra Leone—Government Gold and Diamond Office.
Singapore—Singapore Customs.
South Africa—South African Diamond Board.
Sri Lanka—National Gem and Jewellery Authority.
Swaziland—Office of the Commissioner of Mines.
Switzerland—State Secretariat for Economic Affairs.
Chinese Taipei—Bureau of Foreign Trade.
Tanzania—Commissioner for Minerals.
Thailand—Ministry of Commerce.
Togo—Ministry of Mines and Geology.
Turkey—Istanbul Gold Exchange.
Ukraine—State Gemological Centre of Ukraine.
United Arab Emirates—Dubai Metals and Commodities Center.
United States of America—Importing Authority—United States Bureau of Customs and Border Protection; Exporting Authority—Bureau of the Census.
Vietnam—Ministry of Trade.
Zimbabwe—Ministry of Mines and Mining Development.

This notice shall be published in the **Federal Register**.

Dated: October 31,2011.

William J. Burns,

Deputy Secretary of State, Department of State.

[FR Doc. 2012–11447 Filed 5–10–12; 8:45 am]

BILLING CODE 4710–07–P

DEPARTMENT OF STATE

[Public Notice: 7879]

Shipping Coordinating Committee; Notice of Committee Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 10:00 a.m. on Thursday, May 31st, 2012, in Room 1200 of the United States Coast Guard Headquarters Building, 2100 Second Street SW., Washington, DC 20593–7126. The primary purpose of the meeting is to prepare for the sixty-second Session of the International Maritime Organization (IMO) Technical Co-operation Committee (TCC 62) to be held at the IMO Headquarters, United Kingdom from June 6 to June 8, 2012 and the one hundred and eighth Session of the IMO Council Session (C 108) to be held at the IMO Headquarters, United Kingdom, from June 11 to June 14, 2012.

The agenda items to be discussed include:

Sixty-Second Sesson of the Technical Co-Operation Committee

—Adoption of the agenda
—Work of other bodies and organizations
—Integrated Technical Co-operation Programme: Biennial report on 2010–2011
—Sustainable financing of the Integrated Technical Co-operation Programme
—Linkage Between the Integrated Technical Co-operation Programme and the Millennium Development Goals
—Partnerships for progress
—Voluntary IMO Member State Audit Scheme
—Integration of women in the maritime sector
—Global maritime training institutions
—Impact Assessment Exercise 2008–2011
—Application of the Committee's Guidelines
—Work Programme
—Any other business
—Election of the Chairman and the Vice-Chairman for 2013
—Consideration of the report of the Committee on its sixty-second session

One Hundred and Eighth Session of Council

—Adoption of the agenda
—Report of the Secretary-General on credentials
—Strategy, planning and reform
—Periodic review of administrative requirements in mandatory IMO instruments
—Resource Management
—Human resource matters, including amendments to the Staff Regulations ending 31 December 2011
—Accounts and audit: Final accounts for the financial period ending 31 December 2011
—Report on investments
—Report on arrears of contributions and of advances to the Working Capital Fund and on the implementation of Article 61 of the IMO Convention
—Budget considerations for 2012 and 2013
—Development of a long-term plan for the future financial sustainability of the Organization
—Voluntary IMO Member State Audit Scheme
—Consideration of the report of the Marine Environment Protection Committee
—Consideration of the report of the Legal Committee
—Consideration of the report of the Maritime Safety Committee
—Consideration of the report of the Technical Co-operation Committee
—Technical Co-operation Fund: report on activities of the 2010–2011 programme
—World Maritime University:
—Report of the Board of Governors
—Budget
—Financial sustainability
—Appointment of the Chancellor
—IMO International Maritime Law Institute:
—Report of the Board of Governors
—Budget
—Preliminary review of the IMLI Statute
—Appointment of the Chairman of the Governing Board
—Protection of vital shipping lanes
—External relations:
—Relations with the United Nations and the specialized agencies
—Joint Inspection Unit
—Relations with intergovernmental organizations
—Relations with non-governmental organizations
—World Maritime Day
—International Maritime Prize
—IMO Award for Exceptional Bravery at Sea
—Report on the status of the Convention and membership of the Organization
—Report on the status of conventions and other multilateral instruments in respect of which the Organization performs functions
—Place, date and duration of the next session of the Council
—Supplementary agenda items, if any

Members of the public may attend this meeting up to the seating capacity of the room. To facilitate the building security process, those who plan to attend should contact the meeting coordinator; LCDR Matthew Frazee by email at *matthew.p.frazee@uscg.mil*, by phone at (202) 372–1376 or in writing at Commandant (CG–52), U.S. Coast Guard Headquarters, 2100 2nd Street SW., STOP 7126, Room 1200, Washington, DC 20593–7126 not later than 72 hours before the meeting. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Headquarters building. The Headquarters building is accessible by taxi and privately owned conveyance (public transportation is not generally available).

However, parking in the vicinity of the building is extremely limited. Additional information regarding this and other IMO SHC public meetings may be found at: *www.uscg.mil/imo*.

Dated: May 7, 2012.

Brian Robinson,

Executive Secretary, Shipping Coordinating Committee, Department of State.

[FR Doc. 2012–11504 Filed 5–10–12; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending April 7, 2012

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2012–0049.

Date Filed: April 3, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 24, 2012.

Description: Application of ACT Havayollari A.S. d/b/a ACT Airlines requesting a foreign air carrier permit to enable ACT Airlines to operate charter foreign air transportation of property and mail between a point or points in Turkey, via intermediate points, and points in the United States and beyond, and other charters. ACT Airlines also requests (1) exemption authority, to the extent necessary to enable it to hold out and provide the service described above; and (2) such additional or other relief as the Department may deem necessary or appropriate.

Docket Number: DOT–OST–2012–0050.

Date Filed: April 3, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 24, 2012.

Description: Application of Jeju Air Co., Ltd. requesting an exemption and foreign air carrier permit authorizing it to engage in scheduled foreign air transportation of persons, property and mail from points behind the Republic of Korea via the Republic of Korea and intermediate points, to a point or points in the United States and beyond, to the full extent permitted by the U.S.-Republic of Korea Open Skies Agreement; as well as charter flights.

Docket Number: DOT–OST–2012–0051.

Date Filed: April 3, 2012.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 24, 2012.

Description: Application of Airfix Aviation Oy (''Airfix'') requesting a foreign air carrier permit to engage in on-demand charter transportation of passengers and property between point(s) in Finland and point(s) in the United States, foreign air transportation of persons and property between any points in a Member State of the European Union and any points in the United States coextensive with rights provided under U.S. EC Air Transport Agreement, and other charter transportation. Airfix further requests a corresponding exemption enabling it to provide the service described above pending issuance of a foreign air carrier permit.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–11278 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending March 31, 2012

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2012–0047.

Date Filed: March 27, 2012.

Due Date for Answers, Conforming Applications, or Motion To Modify Scope: April 17, 2012.

Description

Application of Joint Stock Company Aircompany ''Yakutia'' (''Yakutia'') requesting an exemption and a foreign air carrier permit authorizing Yakutia to engage in scheduled foreign air transportation of persons, property, and mail between any point or points in the Russian Federation and any point or points in Alaska. Yakutia further requests that its exemption and permit authorize it to engage in charter foreign air transportation of persons, property and mail between any point or points in the Russian Federation and any point or points in the United States and to conduct other charter trips in foreign air transportation.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–11281 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending April 21, 2012

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1382 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number: DOT–OST–2012–0059.

Date Filed: April 16, 2012.

Parties: Members of the International Air Transport Association.

Subject: PTC COMP Mail Vote 705, Resolution 024d, Currency Names, Codes, Rounding Units and Acceptability of Currencies, Azerbaijan, (Memo 1671).

Intended Effective Date: 1 May 2012.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–11285 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending April 14, 2012

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1382 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number: DOT–OST–2012–0055.

Date Filed: April 11, 2012.

Parties: Members of the International Air Transport Association.

Subject: Mail Vote 704—Resolution 012, Glossary of Terms, (Memo 1670).

Intended Effective Date: 1 May 2012.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2012–11282 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Requirements for Recognizing the Aviation and Aerospace Innovation in Science and Engineering Award

AGENCY: Office of the Secretary of Transportation, U.S. Department of Transportation.

ACTION: Notice of the announcement of Requirements for the Secretary of Transportation's RAISE (Recognizing

Aviation and Aerospace Innovation in Science and Engineering) Award.

Authority: 15 U.S.C. 3719 (America COMPETES Act).

Award Approving Official: Ray LaHood, Secretary of Transportation.

SUMMARY: Pursuant to a recommendation by the DOT's Future of Aviation Advisory Committee, the Secretary of Transportation is announcing an award to recognize students who develop unique scientific and engineering innovations in aerospace. With this award, the Secretary of Transportation intends to create an incentive for participants at high schools, colleges, and universities to develop innovative solutions to aviation and aerospace issues, and to share those innovations with the broader community.

DATES: Effective on April, 2012 to October, 2012.

FOR FURTHER INFORMATION CONTACT: Patricia Watts, Ph.D., Federal Aviation Administration, (609) 485–5043 or James Brough, Federal Aviation Administration, (781) 238–7027.

SUPPLEMENTARY INFORMATION: *Subject of Challenge Competition:* The RAISE Award will recognize innovative scientific and engineering achievements that will have a significant impact on the future of aerospace or aviation. The award is open to students at the high school, undergraduate, and graduate levels. Following an open solicitation, the Award Review Board Chair will submit nominations to the Secretary of Transportation for final consideration.

Eligibility Rules for Participating in the Competition:

Selection Criteria

1. Candidates must be U.S. citizens or permanent residents and must have been enrolled for at least two semesters at a high school (or equivalent approved home school program), college, or university to be eligible to receive the award.

2. Students may participate as individuals or in groups. Each member of the group must meet the above criteria.

Further, to be eligible to win the award under this announcement, every candidate—

1. Shall first submit a project in the competition under the rules promulgated by the U.S. Department of Transportation;

2. Shall agree to execute indemnifications and waivers of claims against the federal government as provided in the registration materials;

3. May not be a Federal entity or Federal employee acting within the scope of employment; and

4. May not be an employee of the Department of Transportation or the Federal Aviation Administration.

A candidate shall not be deemed ineligible because the individual used Federal facilities or consulted with Federal employees during a competition, if the facilities and employees are made available to all individuals participating in the competition on an equitable basis.

Rules for Participants:

Rules for this competition will be available for download at *www.challenge.gov.* There is no charge to enter. A submission package will consist of the following sections in this order:

1. Nomination letter from at least one teacher, advisor, faculty member, and others as appropriate. The nomination letter(s) must communicate the following accomplishments in two areas:

Technical Merit of the Concept

Evidence of technical merit based upon teacher (parent or legal guardian in the case of home schooled applicants), advisor, or faculty nomination and evaluation of the submitted proposal, written paper, and/or reports.

Professionalism and Leadership

Evidence of professionalism and leadership can be in the form of, but not limited to:

(1) Membership and offices held in various groups

(2) Presentations made to various groups, meetings, and at symposia

(3) Leadership in student professional activities

(4) Community outreach activities

2. An overall summary of the innovation, not to exceed one page, which includes a statement of the impact that the innovation will have on the field of aviation or aerospace;

3. A copy of the student's academic transcript or certified grade report (as applicable);

4. A copy of the paper(s) and related materials describing the innovative concept written by the student(s) being nominated (no page limit).

All materials should be forwarded with a cover letter to the attention of: Patricia Watts, Ph.D., Centers of Excellence Program Director, Federal Aviation Administration, L–28, FAA William J. Hughes Technical Center, Atlantic City International Airport, NJ 08405.

Hardcopy is preferred; however, the package also may be transmitted by email to *Patricia.Watts@FAA.gov.* All entries must be received by 11:59 p.m. Pacific standard time on July 27, 2012. Award administrators assume no responsibility for lost or untimely submissions for any reason.

Award:

The winner will be announced in October. A trophy with the winner's name and date of award will be displayed at the Department of Transportation and a display copy of the trophy will be sent to the winner's school/college/university. An additional trophy will be awarded to the individual or team.

Basis Upon Which the Winner Will Be Selected:

All submissions will be initially reviewed by the FAA Center for Excellence (COE) Program Director upon receipt to determine if the submissions meet the eligibility requirements. Registration packages meeting the eligibility requirements will be judged by advisory panels consisting of academic experts, government officials including FAA, DOT, and others. The advisory panels will select the most highly qualified submissions and present them to the Secretary of the Department of Transportation, who will select the winning entrant.

Submissions will be judged on the following criteria:

Originality:

- Is this concept new or a variation of an existing idea, and in what way(s)?
- How is this work unique?
- Was the concept developed independently or in cooperation with others?

Impact:

- To what extent has this contribution:
  - Made a fundamental change?
  - Made a major contribution to the future of the aviation environment?

Practicality:

- Who directly benefits from this work?
- Can this program or activity be implemented in a practical fashion?
- What are the costs anticipated to be incurred and saved by executing this concept?

Measurability:

- How has this individual/group measured the impact on the aviation environment?
- To what extent does the innovation result in measurable improvements?

Applicability:

- Can this effort be scaled?
- Is this work specific to one region, various regions, or to the entire nation?
- How does this activity lead to future changes in aviation?

Technical Merit:

• Has the submission presented a clear understanding of the associated problems?

• Has the submission developed a logical and workable solution and approach to solving the problem/s?

• What are the most significant aspects of this concept?

• Has the submission clearly demonstrated the breadth of impact of the innovation?

All factors are important and will be given consideration, but the advisory panels will give the ''technical merit'' factor the most weight in the screening process. The Secretary of Transportation retains sole discretion to select the winning entrant.

Additional Information:

Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless such use is consistent with the purpose of their grant award.

Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

Issued On: April 30, 2012.

Susan L. Kurland,

Assistant Secretary of Aviation and International Affairs.

[FR Doc. 2012–11465 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Air Traffic Procedures Advisory Committee

AGENCY: Federal Aviation Administration (FAA), DOT.

SUMMARY: The FAA is issuing this notice to advise the public that a meeting of the Federal Aviation Administration Air Traffic Procedures Advisory Committee (ATPAC) will be held to review present air traffic control procedures and practices for standardization, revision, clarification, and upgrading of terminology and procedures. Class B airspace will be a major topic of discussion on the ATPAC Agenda.

DATES: The meeting will be held Tuesday, June 5, Wednesday, June 6, and Thursday, June 7, 2012 from 8:30 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be held at the Holiday Inn, 801355 North Harbor Drive, San Diego, CA 92101.

FOR FURTHER INFORMATION CONTACT: Mr. Gary Norek, ATPAC Executive Director, 800 Independence Avenue SW., Washington, DC 20591.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App.2), notice is hereby given of a meeting of the ATPAC to be held Tuesday, June 5, Wednesday, June 6, and Thursday, June 7, 2012 from 8:30 a.m. to 5:00 p.m.

The agenda for this meeting will cover a continuation of the ATPAC's review of present air traffic control procedures and practices for standardization, revision, clarification, and upgrading of terminology and procedures. It will also include:

1. Approval of Minutes;
2. Submission and Discussion of Areas of Concern;
3. Discussion of Potential Safety Items;
4. Report from Executive Director;
5. Class B Airspace;
6. Items of Interest; and
7. Discussion and agreement of location and dates for subsequent meetings.

Attendance is open to the interested public but limited to space available. With the approval of the Chairperson, members of the public may present oral statements at the meeting. Persons desiring to attend and persons desiring to present oral statement should notify Mr. Richard Jehlen no later than May 23, 2012. Any member of the public may present a written statement to the ATPAC at any time at the address given above.

Issued in Washington, DC, on May 3, 2012.

Ellen Crum,

Acting Executive Director, Air Traffic Procedures Advisory Committee.

[FR Doc. 2012–11397 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership Availability in the National Parks Overflights Advisory Group Aviation Rulemaking Committee

ACTION: Notice.

SUMMARY: The National Park Service (NPS) and the Federal Aviation Administration (FAA), as required by the National Parks Air Tour Management Act of 2000, established the National Parks Overflights Advisory Group (NPOAG) in March 2001. The NPOAG was formed to provide continuing advice and counsel with respect to commercial air tour operations over and near national parks. This notice informs the public of six vacancies (due to completion of membership on October 9, 2012) on the NPOAG [now the NPOAG Aviation Rulemaking Committee (ARC)] for members representing general aviation (one vacancy), commercial air tour operators (two vacancies), environmental concerns (two vacancies), and Native American tribal concerns (one vacancy) and invites interested persons to apply to fill the vacancies.

DATES: Persons interested in serving on the NPOAG ARC should contact Mr. Barry Brayer in writing and postmarked or emailed on or before June 8, 2012.

FOR FURTHER INFORMATION CONTACT: Barry Brayer, AWP–1SP, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, P.O. Box 92007, Los Angeles, CA 90009–2007, telephone: (310) 725–3800, email: *Barry.Brayer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106–181. The Act required the establishment of the advisory group within 1 year after it's enactment. The advisory group was established in March 2001, and is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairman of the advisory group.

The advisory group provides ''advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) At the request of the Administrator and the Director, safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands.''

Members of the advisory group may be allowed certain travel expenses as authorized by section 5703 of Title 5,

United States Code, for intermittent Government service.

By FAA Order No. 1110–138, signed by the FAA Administrator on October 10, 2003, the NPOAG became an Aviation Rulemaking Committee (ARC). FAA Order No. 1110–138, was amended and became effective as FAA Order No. 1110–138A, on January 20, 2006.

The current NPOAG ARC is made up of one member representing general aviation, three members representing the commercial air tour industry, four members representing environmental concerns, and two members representing Native American tribal concerns. Current members of the NPOAG ARC are: Heidi Williams representing general aviation; Alan Stephen, Elling Halvorson, and Matthew Zuccaro representing commercial air tour concerns; Chip Dennerlein, Gregory Miller, Bryan Faehner, and Dick Hingson representing environmental interests; Rory Majent and Ray Russell, representing Native American tribes.

In order to retain balance within the NPOAG ARC, the FAA and NPS invite persons interested in serving on the ARC to represent general aviation, commercial air tour operators, environmental concerns, or Native American tribal concerns, to contact Mr. Barry Brayer (contact information is written above in **FOR FURTHER INFORMATION CONTACT**).

Requests to serve on the ARC must be made to Mr. Brayer in writing and postmarked or emailed on or before June 8, 2012. The request should indicate whether or not you are a member of an association or group representing general aviation, commercial air tours, environmental concerns, or Native American tribal concerns or have another affiliation with issues relating to aircraft flights over national parks. The request should also state what expertise you would bring to the NPOAG ARC as related to the vacancy you are seeking to fill (e.g., general aviation). The term of service for NPOAG ARC members is 3 years.

Issued in Hawthorne, CA, on April 30, 2012.

Barry Brayer,

NPOAG Chairman, Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 2012–11402 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0118]

Agency Information Collection Activities; Extension of a Currently-Approved Information Collection Request: Motor Carrier Identification Report

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval. The FMCSA requests approval to extend an ICR entitled, ''Motor Carrier Identification Report,'' which is used to identify FMCSA regulated entities, prioritize the agency's activities, aid in assessing the safety outcomes of those activities, and for statistical purposes.

On February 6, 2012, FMCSA published a **Federal Register** notice allowing for a 60-day comment period on the ICR. No comments were received.

DATES: Please send your comments by June 11, 2012. OMB must receive your comments by this date in order to act quickly on the ICR.

ADDRESSES: All comments should reference Federal Docket Management System (FDMS) Docket Number FMCSA–2012–0118. Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Ms. Vivian Oliver, Transportation Specialist, Office of Information Technology, Operations Division, Department of Transportation, Federal Motor Carrier Safety Administration, West Building 6th Floor, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: 202–366–2974; email Address: *vivian.oliver@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Motor Carrier Identification Report.

OMB Control Number: 2126–0013.

Type of Request: Extension of a currently-approved information collection.

Respondents: Motor carriers, commercial motor vehicle drivers, and intermodal equipment providers.

Estimated Number of Respondents: 447,109.

Estimated Time per Response: To complete Form MCS–150, motor carriers will need 20 minutes the first time they file this report and 7.5 minutes for the biennial update. To complete Form MCS–150B (HM Safety Permit Application), interstate HM carriers that have already completed the Form MCS–150 will need 6 minutes to complete this report and intrastate HM carriers that have never completed a Form MCS–150 will need about 16 minutes to complete it and 5 minutes for the biennial update. Form MCS–150C—Intermodal Equipment Providers will need 20 minutes the first time they file this report and 7.5 minutes for the biennial update.

Expiration Date: July 31, 2012.

Frequency of Response: Biennially.

Estimated Total Annual Burden: 93,792 hours [93,534 hours for Form MCS–150 + 249 hours for Form MCS–150B + 9 hours for Form MCS–150C = 93,792 hours].

Background: Title 49, United States Code Section 504(b)(2) provides the Secretary of Transportation (Secretary) with authority to require carriers, lessors, associations, or classes of these entities to file annual, periodic, and special reports containing answers to questions asked by the Secretary. The Secretary may also prescribe the form of records required to be prepared or compiled and the time period during which records must be preserved (See § 504(b)(1) and (d)). The FMCSA will use this data to administer its safety programs by establishing a database of entities that are subject to its regulations. This database necessitates that these entities notify the FMCSA of their existence. For example, under 49 CFR 390.19(a), FMCSA requires all motor carriers beginning operations to file a Form MCS–150 entitled, ''Motor Carrier Identification Report.'' This report is filed by all motor carriers conducting operations in interstate or international commerce before beginning operations. It asks the

respondent to provide the name of the business entity that owns and controls the motor carrier operation, address and telephone of principal place of business, assigned identification number(s), type of operation, types of cargo usually transported, number of vehicles owned, term leased and trip leased, driver information, and certification statement signed by an individual authorized to sign documents on behalf of the business entity.

The Department of Transportation (DOT) and Related Agencies Appropriations Act for fiscal year 2002 (DOT Appropriations Act) (Pub. L. 107–87, 115 Stat. 833) directed the agency to issue an interim final rule (IFR) to ensure that new entrant motor carriers are knowledgeable about the Federal Motor Carrier Safety Regulations (FMCSRs) and standards.

On June 30, 2004, the agency issued a final rule entitled, ''Federal Motor Carrier Safety Regulations: Hazardous Materials Safety Permits,'' (69 FR 39350) which required all HM carriers (both interstate and intrastate) to complete and file the Form MCS–150B entitled, ''Combined Motor Carrier Identification Report and HM Permit Application,'' to obtain a safety permit to transport hazardous materials. The safety program under 49 CFR 390.19(a) also requires all HM permitted carriers to complete Form MCS–150B in place of the current Form MCS–150 to ''renew'' both their permit and their DOT numbers according to the DOT number renewal schedule.

On December 17, 2008, FMCSA issued a final rule entitled, ''Requirements for Intermodal Equipment Providers and for Motor Carriers and Drivers Operating Intermodal Equipment,'' (73 FR 76794) which required all intermodal equipment providers to complete Form MCS–150C entitled, ''Intermodal Equipment Provider Identification Report'' in order to register with the Agency and receive a USDOT number. FMCSA now regulates intermodal equipment providers and requires them to complete Form MCS–150C, instead of the current Form MCS–150. In addition, intermodal equipment providers must complete Form MCS–150C to update their USDOT number record according to the USDOT number update schedule in 49 CFR 390.19.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued on: April 25, 2012.

Kelly Leone,

Associate Administrator for Research and Information Technology.

[FR Doc. 2012–11456 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No FMCSA–2011–0097]

Pilot Program on NAFTA Trucking Provisions

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; request for public comment.

SUMMARY: FMCSA announces and requests public comment on data and information concerning the Pre-Authorization Safety Audits (PASA) for three motor carriers that applied to participate in the Agency's long-haul pilot program to test and demonstrate the ability of Mexico-domiciled motor carriers to operate safely in the United States beyond the municipalities in the United States on the United States-Mexico international border or the commercial zones of such municipalities. This action is required by the ''U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007'' and all subsequent appropriations.

DATES: Comments must be received on or before May 21, 2012.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2011–0097 by any one of the following methods: *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, (M–30), U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., West Building, Ground Floor, Room 12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. All submissions must include the Agency name and docket number for this notice. See the ''Public Participation'' heading below for instructions on submitting comments and additional information.

Note that all comments received, including any personal information provided, will be posted without change to *http://www.regulations.gov.* Please see the ''Privacy Act'' heading below.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground floor of the DOT Headquarters Building at 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act System of Records Notice for the DOT Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316).

Public Participation: The *http://www.regulations.gov* Web site is generally available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the ''help'' section of the *http://www.regulations.gov* Web site. Comments received after the comment closing date will be included in the docket, and will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Marcelo Perez, FMCSA, North American Borders Division, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Telephone (512) 916–5440 Ext. 228; email *marcelo.perez@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

On May 25, 2007, the President signed into law the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (the Act), (Pub. L. 110–28, 121 Stat. 112, 183, May 25, 2007). Section 6901 of the Act requires that certain actions be taken by the Department of Transportation (the Department) as a condition of obligating or expending appropriated funds to grant authority to Mexico-domiciled motor carriers to operate beyond the municipalities in the United States on the United States-Mexico international border or the commercial zones of such

municipalities (border commercial zones).

On July 8, 2011, FMCSA announced in the **Federal Register** [76 FR 40420] its intent to proceed with the initiation of a U.S.-Mexico cross-border long-haul trucking pilot program to test and demonstrate the ability of Mexico-domiciled motor carriers to operate safely in the United States beyond the border commercial zones as detailed in the Agency's April 13, 2011, **Federal Register** notice [76 FR 20807]. The pilot program is a part of FMCSA's implementation of the North American Free Trade Agreement (NAFTA) cross-border long-haul trucking provisions in compliance with section 6901(b)(2)(B) of the Act. FMCSA reviewed, assessed, and evaluated the required safety measures as noted in the July 8, 2011, notice and considered all comments received on or before May 13, 2011, in response to the April 13, 2011, notice. Additionally, to the extent practicable, FMCSA considered comments received after May 13, 2011.

In accordance with section 6901(b)(2)(B)(i) of the Act, FMCSA is required to publish in the **Federal Register,** and provide sufficient opportunity for public notice and comment comprehensive data and information on the PASAs conducted of motor carriers domiciled in Mexico that are granted authority to operate beyond the border commercial zones. This notice serves to fulfill this requirement.

FMCSA is publishing for public comment the data and information relating to three PASAs that were completed. FMCSA announces that the Mexico-domiciled motor carriers listed in Table 1 successfully completed the PASA. Notice of this completion was also published in the FMCSA Register.

Tables 2, 3 and 4 all titled (''Successful Pre-Authorization Safety Audit (PASA) Information'') set out additional information on the carrier(s) noted in Table 1. A narrative description of each column in the tables is provided as follows:

A. *Row Number in the Appendix for the Specific Carrier:* The row number for each line in the tables.

B. *Name of Carrier:* The legal name of the Mexico-domiciled motor carrier that applied for authority to operate in the United States (U.S.) beyond the border commercial zones and was considered for participation in the long-haul pilot program.

C. *U.S. DOT Number:* The identification number assigned to the Mexico-domiciled motor carrier and required to be displayed on each side of the motor carrier's power units. If granted provisional operating authority, the Mexico-domiciled motor carrier will be required to add the suffix ''X'' to the ending of its assigned U.S. DOT Number for those vehicles approved to participate in the pilot program.

D. *FMCSA Register Number:* The number assigned to the Mexico-domiciled motor carrier's operating authority as found in the FMCSA Register.

E. *PASA Initiated:* The date the PASA was initiated.

F. *PASA Completed:* The date the PASA was completed.

G. *PASA Results:* The results upon completion of the PASA. The PASA receives a quality assurance review before approval. The quality assurance process involves a dual review by the FMCSA Division Office supervisor of the auditor assigned to conduct the PASA and by the FMCSA Service Center New Entrant Specialist designated for the specific FMCSA Division Office. This dual review ensures the successfully completed PASA was conducted in accordance with FMCSA policy, procedures and guidance. Upon approval, the PASA results are uploaded into the FMCSA's Motor Carrier Management Information System (MCMIS). The PASA information and results are then recorded in the Mexico-domiciled motor carrier's safety performance record in MCMIS.

H. *FMCSA Register:* The date FMCSA published notice of a successfully completed PASA in the FMCSA Register. The FMCSA Register notice advises interested parties that the application has been preliminarily granted and that protests to the application must be filed within 10 days of the publication date. Protests are filed with FMCSA Headquarters in Washington, DC. The notice in the FMCSA Register lists the following information:

a. Current registration number (e.g., MX–123456);

b. Date the notice was published in the FMCSA Register;

c. The applicant's name and address; and

d. Representative or contact information for the applicant.

The FMCSA Register may be accessed through FMCSA's Licensing and Insurance public Web site at *http://li-public.fmcsa.dot.gov/,* and selecting FMCSA Register in the drop down menu.

I. *U.S. Drivers:* The total number of the motor carrier's drivers approved for long-haul transportation in the United States beyond the border commercial zones.

J. *U.S. Vehicles:* The total number of the motor carrier's power units approved for long-haul transportation in the United States beyond the border commercial zones.

K. *Passed Verification of 5 Elements (Yes/No):* A Mexico-domiciled motor carrier will not be granted provisional operating authority if FMCSA cannot verify all of the following five mandatory elements. FMCSA must:

a. Verify a controlled substances and alcohol testing program consistent with 49 CFR part 40;

b. Verify a system of compliance with hours-of-service rules of 49 CFR part 395, including recordkeeping and retention;

c. Verify the ability to obtain financial responsibility as required by 49 CFR 387, including the ability to obtain insurance in the United States;

d. Verify records of periodic vehicle inspections; and

e. Verify the qualifications of each driver the carrier intends to use under such authority, as required by 49 CFR parts 383 and 391, including confirming the validity of each driver's Licencia Federal de Conductor and English language proficiency.

L. *If No, Which Element Failed:* If FMCSA cannot verify one or more of the five mandatory elements outlined in 49 CFR part 365, Appendix A, Section III, this column will specify which mandatory element(s) cannot be verified.

Please note that for items L through P below, during the PASA, after verifying the five mandatory elements discussed in item K above, FMCSA will gather information by reviewing a motor carrier's compliance with ''acute and critical'' regulations of the Federal Motor Carrier Safety Regulations (FMCSRs) and Hazardous Materials Regulations (HMRs). Acute regulations are those where noncompliance is so severe as to require immediate corrective actions by a motor carrier regardless of the overall basic safety management controls of the motor carrier. Critical regulations are those where noncompliance relates to management and/or operational controls. These regulations are indicative of breakdowns in a carrier's management controls. A list of acute and critical regulations is included in 49 CFR part 385, Appendix B, Section VII.

Parts of the FMCSRs and HMRs having similar characteristics are combined together into six regulatory areas called ''factors.'' The regulatory factors are intended to evaluate the adequacy of a carrier's management controls.

M. *Passed Phase 1, Factor 1:* A ''yes'' in this column indicates the carrier has successfully met Factor 1 (listed in part 365, Subpart E, Appendix A, Section IV(f)). Factor 1 includes the General Requirements outlined in parts 387 (Minimum Levels of Financial Responsibility for Motor Carriers) and 390 (Federal Motor Carrier Safety Regulations—General).

N. *Passed Phase 1, Factor 2:* A ''yes'' in this column indicates the carrier has successfully met Factor 2, which includes the Driver Requirements outlined in parts 382 (Controlled Substances and Alcohol Use and Testing), 383 (Commercial Driver's License Standards; Requirements and Penalties) and 391 (Qualifications of Drivers and Longer Combination Vehicle (LCV) Driver Instructors).

O. *Passed Phase 1, Factor 3:* A ''yes'' in this column indicates the carrier has successfully met Factor 3, which includes the Operational Requirements outlined in parts 392 (Driving of Commercial Motor Vehicles) and 395 (Hours of Service of Drivers).

P. *Passed Phase 1, Factor 4:* A ''yes'' in this column indicates the carrier has successfully met Factor 4, which includes the Vehicle Requirements outlined in parts 393 (Parts and Accessories Necessary for Safe Operation) and 396 (Inspection, Repair and Maintenance) and vehicle inspection and out-of-service data for the last 12 months.

Q. *Passed Phase 1, Factor 5:* A ''yes'' in this column indicates the carrier has successfully met Factor 5, which includes the hazardous material requirements outlined in parts 171 (General Information, Regulations, and Definitions), 177 (Carriage by Public Highway), 180 (Continuing Qualification and Maintenance of Packagings) and 397 (Transportation of Hazardous Materials; Driving and Parking Rules).

R. *Passed Phase 1, Factor 6:* A ''yes'' in this column indicates the carrier has successfully met Factor 6, which includes Accident History. This factor is the recordable accident rate during the past 12 months. A recordable ''accident'' is defined in 49 CFR 390.5, and means an accident involving a commercial motor vehicle operating on a public road in interstate or intrastate commerce which results in a fatality; a bodily injury to a person who, as a result of the injury, immediately received medical treatment away from the scene of the accident; or one or more motor vehicles incurring disabling damage as a result of the accident requiring the motor vehicle to be transported away from the scene by a tow truck or other motor vehicle.

S. *Number U.S. Vehicles Inspected:* The total number of vehicles (power units) the motor carrier is approved to operate in the United States beyond the border commercial zones that received a vehicle inspection during the PASA. During a PASA, FMCSA inspected all power units to be used by the motor carrier in the pilot program and applied a current Commercial Vehicle Safety Alliance (CVSA) inspection decal, if the inspection is passed successfully. This number reflects the vehicles that were inspected, irrespective of whether the vehicle received a CVSA inspection at the time of the PASA decal as a result of a passed inspection.

T. *Number U.S. Vehicles Issued CVSA Decal:* The total number of inspected vehicles (power units) the motor carrier is approved to operate in the United States beyond the border commercial zones that received a CVSA inspection decal as a result of an inspection during the PASA.

U. *Controlled Substances Collection:* Refers to the applicability and/or country of origin of the controlled substance and alcohol collection facility that will be used by a motor carrier that has successfully completed the PASA.

a. ''US'' means the controlled substance and alcohol collection facility is based in the United States.

b. ''MX'' means the controlled substance and alcohol collection facility is based in Mexico.

c. ''Non-CDL'' means that during the PASA, FMCSA verified that the motor carrier is not utilizing commercial motor vehicles subject to the commercial driver's license requirements as defined in 49 CFR 383.5 (Definition of Commercial Motor Vehicle). Any motor carrier that does not operate commercial motor vehicles as defined in § 383.5 is not subject to DOT controlled substance and alcohol testing requirements.

V. *Name of Controlled Substances and Alcohol Collection Facility:* Shows the name and location of the controlled substances and alcohol collection facility that will be used by a Mexico-domiciled motor carrier who has successfully completed the PASA.

TABLE 1

Row number in Tables 2, 3 and 4 of the Appendix to today's notice	Name of carrier	USDOT No.
1 Higienicos y Desechables	710491 del Bajio SA de CV	
2 Servicios Refrigerados	1052546 International SA de CV	
3 Transportes Del Valle	2208377 De Guadalupe SA de CV	

TABLE 2—SUCCESSFUL PRE-AUTHORIZATION SAFETY AUDIT (PASA) INFORMATION

[See also Tables 3 and 4]

Column A—row No.	Column B—name of carrier	Column C—US DOT No.	Column D—FMCSA register No.	Column E—PASA initiated	Column F—PASA completed	Column G—PASA results	Column H—FMCSA register	Column I—US drivers	Column J—US vehicles
1	Higienicos y Desechables del Bajio SA de CV.	710491	MX–327700	1/20/12	1/25/12	Pass	5/3/12	1	1
2	Servicios Refrigerados Internacionales SA de CV.	1052546	MX–440938	2/29/12	3/20/12	Pass	5/3/12	1	1
3	Transportes Del Valle De Guadalupe SA de CV.	2208377	MX–785563	2/7/12	2/14/12	Pass	5/3/12	1	1

TABLE 3—SUCCESSFUL PRE-AUTHORIZATION SAFETY AUDIT (PASA) INFORMATION
[See also Tables 2 and 4]

Column A—row No.	Column B—name of carrier	Column C—US dot No.	Column D—FMCSA register No.	Column K—passed verification of 5 elements (yes/no)	Column L—if no, which element failed	Column M—Passed phase 1 factor 1	Column N—passed phase 1 factor 2	Column O—passed phase 1 factor 3	Column P—passed phase 1 factor 4
1	Higienicos y Desechables del Bajio SA de CV.	710491	MX–327700	Yes		Pass	Pass	Pass	Pass.
2	Servicios Refrigerados Internacionales SA de CV.	1052546	MX–440938	Yes		Pass	Pass	Pass	Pass.
3	Transportes Del Valle De Guadalupe SA de CV.	2208377	MX–785563	Yes		Pass	Pass	Pass	Pass.

TABLE 4—SUCCESSFUL PRE-AUTHORIZATION SAFETY AUDIT (PASA) INFORMATION
[See also Tables 2 and 3]

Column A—row No.	Column B—name of carrier	Column C—US dot No.	Column D—FMCSA register No.	Column Q—passed phase I factor 5	Column R—passed phase I factor 6	Column S—number US vehicles inspected	Column T—number US vehicles issued CVSA decal	Column U—controlled substance collection	Column V—name of controlled substances and alcohol collection facility
1	Higienicos y Desechables del Bajio SA de CV.	710491	MX–327700	N/A	Pass	1	1	US	RMC Testing Solutions.
2	Servicios Refrigerados Internacionales SA de CV.	1052546	MX–440938	N/A	Pass	1	1	US	RMC Testing Solutions.
3	Transportes Del Valle De Guadalupe SA de CV.	2208377	MX–785563	N/A	Pass	1	1	US	RMC Testing Solutions.

In an effort to provide as much information as possible for review, the application and PASA results for this carrier are posted at the Agency's Web site for the pilot program at *http://www.fmcsa.dot.gov/intl-programs/trucking/Trucking-Program.aspx.* For carriers that participated in the Agency's demonstration project that ended in 2009, copies of the previous PASA and compliance review, if conducted, are also posted. All documents were redacted so that personal information regarding the drivers is not released. Sensitive business information, such as the carrier's tax identification number, is also redacted. In response to previous comments received regarding the PASA notice process, FMCSA also posted copies of the vehicle inspections conducted during the PASA in the PASA document.

A list of the carrier's vehicles approved by FMCSA for use in the pilot program is also available at the above referenced Web site.

The Agency acknowledges that through the PASA process it determined that Higienicos y Desechables del Bajio Sa de CV and Servicios Refrigerados Internacionales SA de CV have affiliations with additional companies that the carriers failed to note in their initial applications. An attachment to each respective PASA provides information regarding these affiliations and is available on FMCSA's Web site. FMCSA has confirmed that the companies affiliated with these two carriers are in good standing or are inactive. FMCSA has also determined that neither of these companies is involved in any effort to hide previous non-compliance or safety problems.

Additionally, the applications from Higienicos y Desechables del Bajio SA de CV and Transportes Del Valle de Guadalupe SA de CV reflect an incorrect telephone number for the drug and alcohol collection consortium. FMCSA discovered the discrepancy and the carrier's records were updated to reflect this corrected information. Lastly, Servicios Refrigerados Internacionales SA de CV listed Medtox as their drug and alcohol consortium on their application. However, during the PASA it was determined that Medtox is the name of the testing laboratory used by this carrier, and its consortium is RMC Testing Solutions. FMCSA's records have been updated to reflect this information.

To date, no carriers have failed the PASA. The Act only requires publication of data for carriers receiving operating authority, as failure to successfully complete the PASA precludes the carrier from being granted authority to participate in the long-haul pilot program. FMCSA will, however, publish this information to show motor carriers that failed to meet U.S. safety standards.

Request for Comments

In accordance with the Act, FMCSA requests public comment from all interested persons on the PASA information presented in this notice. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, the FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

FMCSA notes that under its regulations, preliminary grants of authority, pending the carrier's showing of compliance with insurance and process agent requirements and the resolution of any protests, are publically

noticed through publication in the FMCSA Register. Any protests of such grants must be filed within 10 days of publication of notice in the FMCSA Register.

Issued on: May 7, 2012.

Anne S. Ferro,

Administrator.

[FR Doc. 2012–11454 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2012–0042]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 19 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions will enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions are effective May 11, 2012. The exemptions expire on May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov*.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone may search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf*.

Background

On March 23, 2012, FMCSA published a notice of receipt of Federal diabetes exemption applications from 19 individuals and requested comments from the public (77 FR 17111). The public comment period closed on April 23, 2012, and no comments were received.

FMCSA has evaluated the eligibility of the 19 applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current requirement for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible. The September 3, 2003 (68 FR 52441), **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777), **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These 19 applicants have had ITDM over a range of 1 to 36 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the March 23, 2012, **Federal Register** notice and they will not be repeated in this notice.

Discussion of Comments

FMCSA did not receive any comments in this proceeding.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes requirement in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual

provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Conclusion

Based upon its evaluation of the 19 exemption applications, FMCSA exempts, Joseph A. Bailey (VA), Patrick J. Beasley (MN), Tounce H. Gaskin (CT), Joel Gonzalez (CA), John G. Hager, Jr. (NJ), Brian R. Hallisey (MA), Charles C. Karver (MN), Benjamin Kimbrough, Jr. (KS), Kevin T. Kruchan (OH), Jeffrey J. Lawrie (OH), Raymond Pittman, Jr. (IL), Christopher M. Rieman (MN), Daniel J. Russell (OH), Donald L. Russell, Jr. (MD), Robert J. Smith (PA), Robert J. Socha (NE), Brian A. Tatum (MS), Thomas C. Torbett, (MO) and Terry R. Wilker (MN) from the ITDM requirement in 49 CFR 391.41(b)(3), subject to the conditions listed under ''Conditions and Requirements'' above.

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption will be valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: April 30, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–11458 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0107]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from 23 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before June 11, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2012–0107using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 23 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by the statutes.

Qualifications of Applicants

Christopher M. Anderson

Mr. Anderson, age 37, has had ITDM since 1996. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Anderson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Anderson meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Arkansas.

Matthew R. Bagwell

Mr. Bagwell, 21, has had ITDM since 1995. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bagwell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bagwell meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from New York.

Gary L. Bradburn

Mr. Bradburn, 56, has had ITDM since 2002. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bradburn understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bradburn meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2012 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Virginia.

Eric J. Bright

Mr. Bright, 31, has had ITDM since 1998. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bright understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bright meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Jeffrey M. Burgess

Mr. Burgess, 36, has had ITDM since 1988. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Burgess understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Burgess meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Montana.

Roberto Castaneda

Mr. Castaneda, 62, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Castaneda understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Castaneda meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from California.

Kyle D. Dale

Mr. Dale, 36, has had ITDM since 1994. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dale understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dale meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class F operator's license from Missouri.

Frank Glenn

Mr. Glenn, 70, has had ITDM since 1978. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Glenn understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Glenn meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Timothy T. Goggleye

Mr. Goggleye, 43, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Goggleye understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Goggleye meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Jose D. Gonzalez

Mr. Gonzalez, 45, has had ITDM since 2000. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gonzalez understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gonzalez meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2012 and certified that he does not have

diabetic retinopathy. He holds a Class C operator's license from California.

Patrick J. Hempel

Mr. Hempel, 50, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hempel understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hempel meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Tennessee.

Matthew M. Horgan

Mr. Horgan, 28, has had ITDM since 1995. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Horgan understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Horgan meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class E operator's license from Missouri.

Mark C. Lucy

Mr. Lucy, 66, has had ITDM since 1986. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Lucy understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Lucy meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Iowa.

Richard M. McMahon

Mr. McMahon, 50, has had ITDM since 2007. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McMahon understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McMahon meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2012 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Georgia.

Kevin N. Mitchell

Mr. Mitchell, 32, has had ITDM since 1996. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mitchell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mitchell meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from Georgia.

Christopher J. Parr

Mr. Parr, 29, has had ITDM since 2007. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Parr understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Parr meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds an operator's license from Indiana.

Gerald Perkins

Mr. Perkins, 41, has had ITDM since 2000. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Perkins understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Perkins meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from California.

Donald L. Philpott

Mr. Philpott, 72, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Philpott understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Philpott meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

John Randolph

Mr. Randolph, 44, has had ITDM since 1979. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Randolph understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Randolph meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist

examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Oklahoma.

Courtney R. Schiebout

Mr. Schriebout, 60, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Schiebout understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Schiebout meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Barry L. Schwab

Mr. Schwab, 49, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Schwab understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Schwab meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class C chauffeur license from Michigan.

Charles L. Spencer

Mr. Spencer, 47, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Spencer understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Spencer meets the vision requirements of 49 CFR 391.41(b)(10). His optometrist examined him in 2012 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from New York.

Curtis W. Stanley

Mr. Stanley, 58, has had ITDM since 2011. His endocrinologist examined him in 2012 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stanley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stanley meets the vision requirements of 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Nebraska.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice. FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 USC. 31136 (e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

Issued on: April 30, 2012.

Larry W. Minor,

Associate Administrative for Policy.

[FR Doc. 2012–11462 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

[1] Section 4129(a) refers to the 2003 notice as a ''final rule.'' However, the 2003 notice did not issue a ''final rule'' but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0380]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 12 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective May 11, 2012. The exemptions expire on May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202)–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–

224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov*.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf*.

Background

On March 23, 2012, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (77 FR 17109). That notice listed 12 applicants' case histories. The 12 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

FMCSA would like to make a correction regarding one of the twelve drivers; Mr. Rojelio Garcia-Pena. Mr. Garcia-Pena's driving record for the last 3 years shows no crashes or convictions for moving violations in a CMV. It was inadvertently stated in the Notice for comments (77 FR 17109) that his driving record showed two crashes.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 12 applications on their merits and made a determination to grant exemptions to each of them.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing requirement red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 12 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, aphakia, complete loss of vision, macular scarring and prosthesis. In most cases, their eye conditions were not recently developed. Seven of the applicants were either born with their vision impairments or have had them since childhood. The five individuals that sustained their vision conditions as adults have had them for a period of 9 to 40 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 12 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 3 to 47 years. In the past 3 years, two of the drivers were involved in crashes, and two were convicted of moving violations in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the March 23, 2012 notice (77 FR 17109).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that

experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 12 applicants, two of the drivers was involved in crashes and two were convicted of moving violations in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 12 applicants listed in the notice of March 23, 2012 (77 FR 17109).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 12 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

FMCSA received no comments in this proceeding.

Conclusion

Based upon its evaluation of the 12 exemption applications, FMCSA exempts Robert J. Ambrose (MA), Clifford W. Doran, Jr. (NC), Scott T. Green (OR), Mark J. Meacham (NC), Ronnie D. Owens (MO), Rojelio Garcia-Pena. (MI), John M. Riley (AL), Jeffrey A. Sheets (AZ), Scotty W. Sparks (KY), Scottie Stewart (MS), Charles E. Stokes (MI), and Timothy J. Sullivan (FL) from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: May 3, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–11444 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0104

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 8 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. The applicants are unable to meet the vision requirement in one eye for various reasons. The reasons are annotated in each applicant's summary in the ''Qualifications of Applicants'' section below. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the Federal vision requirement.

DATES: Comments must be received on or before June 11, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2012–0104 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' FMCSA can renew exemptions at the end of each 2-year period. The 8individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Qualifications of Applicants

Joseph A. Ellis

Mr. Ellis, age 51, has loss of vision in his right eye due to a traumatic injury sustained at age 14. The best corrected visual acuity in his right eye is 20/60, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''Mr. Ellis demonstrates sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Ellis reported that he has driven straight trucks for 6 years, accumulating 22,800 miles. He holds a Class D operator's license from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Matthew G. Epps

Mr. Epps, 35, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/400, and in his left eye, 20/15. Following an examination in 2012, his optometrist noted, ''Mr. Epps has sufficient visiual stability to operate commercial vehicles.'' Mr. Epps reported that he has driven straight trucks for 11 years, accumulating 165,000 miles and tractor-trailer combinations for 1 year, accumulating 19,000 miles. He holds a Class A Commercial Driver's License (CDL) from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Brian R. Gallagher

Mr. Gallagher, 32, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/60, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''In my expert opinion, this person has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Gallagher reported that he has driven straight trucks for 11 years, accumulating 148,500 miles and tractor-trailer combinations for 11 years, accumulating 528,000 miles. He holds a Class A CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Jolene A. Gauger

Ms. Gauger, 29, has had amblyopia in her right eye since birth. The best corrected visual acuity in her right eye is 20/80, and in her left eye, 20/25. Following an examination in 2011, her optometrist noted, ''I certify that in my medical opinion, Jolene Alison Gauger has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Ms. Gauger reported that she has driven straight trucks for 14 years, accumulating 350,000 miles. She holds a Class D operator's license from Wisconsin. Her driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

John F. Lynch

Mr. Lynch, 35, has complete loss of vision in his left eye due to a traumatic injury sustained in the mid 1990s. The visual acuity in his right eye is 20/15. Following an examination in 2012, his ophthalmologist noted, ''In my opinion, he has sufficient vision and meets all the standards that are outlined on the page of criteria that were submitted.'' Mr. Lynch reported that he has driven straight trucks for 9 years, accumulating 280,800 miles. He holds a Class D operator's license from Vermont. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Marcus D. Perkins

Mr. Perkins, 34, has had a retinal detachment in his left eye since 1987. The best corrected visual acuity in his right eye is 20/20, and in his left eye, light perception only. Following an examination in 2012, his optometrist noted, ''I feel Markus has sufficient vision to operate a commercial vehicle.'' Mr. Perkins reported that he has driven straight trucks for 8 months, accumulating 160,000 miles and tractor-

trailer combinations for 10 years, accumulating 1.4 million miles. He holds a Class D chauffeur's license from Louisiana. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Joe Ramirez

Mr. Ramirez, 40, has had a macular scar in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2012, his optometrist noted, ''In my medical opinion, Mr. Ramirez has sufficient vision to operate a commercial vehicle.'' Mr. Ramirez reported that he has driven straight trucks for 4 years, accumulating 320,000 miles and tractor-trailer combinations for 12 years, accumulating 13.5 million miles. He holds a Class A CDL from California. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

John C. Smith

Mr. Smith, 54, has a prosthetic right eye due to a traumatic injury sustained in 1987. The visual acuity in his left eye is 20/20. Following an examination in 2011, his optometrist noted, ''I hereby certify that it is my medical opinion that Mr. Smith has sufficient vision to safely operate a commercial vehicle.'' Mr. Smith reported that he has driven straight trucks for 11 years, accumulating 220,000 miles and tractor-trailer combinations for 26 years, accumulating 10.7 million miles. He holds a Class A CDL from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business June 11, 2012. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable.

In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: May 3, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–11446 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1999–5748; FMCSA–2001–11426; FMCSA–2002–11714; FMCSA–2009–0011; FMCSA–2010–0050]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 11 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective May 30, 2012. Comments must be received on or before June 11, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: FMCSA–1999–5748; FMCSA–2001–11426; FMCSA–2002–11714; FMCSA–2009–0011; FMCSA–2010–0050, using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 11 individuals who have requested renewal of their exemptions in accordance with FMCSA

procedures. FMCSA has evaluated these 11 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Guy M. Alloway (OR)
Joe W. Brewer (SC)
Larry D. Buchanan (NM)
Donald D. Dunphy (VA)
James W. Ellis, 4th (NJ)
David A. Inman (IN)
Jason T. Montoya (NM)
Lawrence C. Moody (NJ)
Stanley W. Nunn (TN)
Bobby C. Spencer (TN)
Kevin R. Stoner (PA)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two-year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 11 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (64 FR 40404; 64 FR 66962; 67 FR 10471; 67 FR 10475; 67 FR 19798; 67 FR 15662; 67 FR 37907; 69 FR 19611; 69 FR 26206; 71 FR 26602; 73 FR 27017; 75 FR 27621; 75 FR 22176; 75 FR 14656; 75 FR 9480; 75 FR 28682). Each of these 11 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by June 11, 2012.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 11 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: April 30, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–11453 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0379]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 17 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement. They are unable to meet the vision requirement in one eye for various reasons. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective May 11, 2012. The exemptions expire on May 12, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between

9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

Background

On March 14, 2012, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (77 FR 15184). That notice listed 17 applicants' case histories. The 17 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 17 applications on their merits and made a determination to grant exemptions to each of them.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing requirement red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 17 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, retinal retinopathy, corneal scar, complete loss of vision, macular scarring and prosthesis. In most cases, their eye conditions were not recently developed. Eight of the applicants were either born with their vision impairments or have had them since childhood. The nine individuals that sustained their vision conditions as adults have had them for a period of 4 to 38 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 17 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 4 to 39 years. In the past 3 years, one of the drivers was involved in crashes, and two were convicted of moving violations in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the March 14, 2012 notice (77 FR 15184).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the

probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 17 applicants, one of the drivers was involved in crashes and two were convicted of moving violations in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 17 applicants listed in the notice of March 14, 2012 (77 FR 15184).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 17 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

FMCSA received no comments in this proceeding.

Conclusion

Based upon its evaluation of the 17 exemption applications, FMCSA exempts David A. Brannon (FL), Robert L. Brauns (IA), Bobby R. Brooks (GA), Melvin D. Clark (GA), Jackie K. Cooper (UT), William C. Dempsey, Jr. (MA), Ryan C. Dugan (NY), Donald J. Garrison (TN), Glenn C. Grimm (NJ), Lee P. Holt (TN), Lance C. Phares (NY), Richard A. Pucker (WI), Mark A. Smith (IA), Randy L. Stevens (GA), Marion Tutt, Jr. (GA), Wade W. Ward (WY) and Jimmy S. Zamora (TX) from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: April 30, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–11445 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0105

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 7 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the Federal vision requirement.

DATES: Comments must be received on or before June 11, 2012.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2012–0105 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please

see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf.*

FOR FURTHER INFORMATION CONTACT:

Elaine M. Papp, Chief,

Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' FMCSA can renew exemptions at the end of each 2-year period. The 7 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Qualifications of Applicants

Charles S. Amyx, Jr.

Mr. Amyx, age 46, had an enucleation of his right eye due to a traumatic incident that occurred at age 15. The best corrected visual acuity in his left eye is 20/15. Following an examination in 2011, his ophthalmologist noted, ''I feel that he would be a safe driver with a CDL and I do not feel that his driving ability would be compromised by the lack of a normally functioniong right eye.'' Mr. Amyx reported that he has driven tractor-trailer combinations for 24 years, accumulating 1.8 million miles. He holds a Class A Commercial Driver's License (CDL) from Louisiana. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Giovanni B. Cerino, Jr.

Mr. Cerino, 50, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/400, and in his left eye, 20/20. Following an examination in 2011, his ophthalmologist noted, ''His exam proves that he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Cerino reported that he has driven tractor-trailer combinations for 26 years, accumulating 4.1 million miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Randall L. Mathis

Mr. Mathis, 40, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/80, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''It is my opinion that this should not affect his ability to drive safely a commercial vehicle under any driving conditions.'' Mr. Mathis reported that he has driven tractor-trailer combinations for 14 years, accumulating 1.3 million miles. He holds a Class A Commercial Driver's License (CDL) from Alabama. His driving record for the last 3 years shows no crashes and no convictions for

Shane N. Maul

Mr. Maul, 31, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/80, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''In my opinion, Mr. Maul has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Maul reported that he has driven straight trucks for 1 year, accumulating 40,000 miles and tractor-trailer combinations for 10 years, accumulating 1 million miles. He holds a Class A CDL from Indiana. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Michael E. McAfee

Mr. McAfee, 28, has congenital eye disease including cataract and amblyopia in his left eye. The best corrected visual acuity in his right eye is 20/15, and in his left eye, count-finger vision. Following an examination in 2012, his optometrist noted, ''It is my opinion that this gentleman has sufficient vision to perform the driving tasks required for a commercial Class A vehicle.'' Mr. McAfee reported that he has driven straight trucks for 10 years, accumulating 50,000 miles. He holds a Class D operator's license from Kentucky. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Dennis D. Pimley

Mr. Pimley, 65, has had a retinal detachment in his left eye since 10 years ago. The best corrected visual acuity in his right eye is 20/200, and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, ''In my medical opinion, Mr. Pimely has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Pimley reported that he has driven straight trucks for 43 years, accumulating 1.8 million miles and tractor-trailer combinations for 22 years, accumulating 1.7 million miles. He holds a Class A CDL from California. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

James E. Sikkink

Mr. Sikkink, 45, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/400, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''In my medical opinion he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Sikkink reported that he has driven straight trucks for 14 years, accumulating 436,800 miles. He holds a Class B CDL from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public

comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business June 11, 2012. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable.

In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: May 3, 2012.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2012–11439 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2012–0025]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: The Federal Transit Administration invites public comment about our intention to request the Office of Management and Budget's (OMB) approval of the following new information collection:

Transit Safety Survey *(OMB Number: 2132–New).*

The **Federal Register** Notice with a 60-day comment period soliciting comments was published on February 27, 2012.

The information obtained from the survey will provide FTA with the opportunity to establish a proactive safety research agenda that will improve the safety of transit systems across the country.

DATES: Comments must be submitted before June 11, 2012. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: LaStar Matthews, Office of Administration, Office of Management Planning, (202) 366–2295.

SUPPLEMENTARY INFORMATION:

Title: Transit Safety Survey.

Abstract: The survey covered in this request will provide FTA with a means to gather data directly from its stakeholders. The information obtained from the survey will be used to improve transit safety research with long-term goals of improving public transit safety and reducing risk for transit properties, transit passengers, and the public in general. The survey will be limited to data collections that solicit voluntary opinions to enable us to effectively address transit safety issue areas, identify safety trends, and structure a responsive and proactive research agenda for FTA.

Estimated Total Annual Burden: 266 hours.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725—17th Street NW., Washington, DC 20503, Attention: FTA Desk Officer.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued: May 2, 2012.

Ann M. Linnertz,

Associate Administrator for Administration.

[FR Doc. 2012–10942 Filed 5–10–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Request for Comment

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), this notice announces that the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review. The ICR describes the nature of the information collection and its expected burden. A **Federal Register** Notice with a 60-day comment period soliciting public comments on the following information collection was published on January 13, 2011 (Federal Register/Vol. 76, No. 9/pp. 2442–2444).

DATES: Submit comments to the Office of Management and Budget (OMB) on or before June 11, 2012.

FOR FURTHER INFORMATION CONTACT: Alan Block at the National Highway Traffic Safety Administration, Office of Behavioral Safety Research (NTI–131), W46–499, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Mr. Block's phone number is 202–366–6401 and his email address is *alan.block@dot.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2127–New.

Title: Demonstration Tests of Different High Visibility Enforcement Models.

Form No.: NHTSA Forms 1121 and 1122.

Type of Review: Regular.

Respondents: Telephone interviews will be administered to residents in each of five selected communities who are drivers, age 18 and older, have access to a residential landline and/or a personal cell phone, and have consumed alcohol in the past year. In-person interviews will be conducted in each of the five selected communities with bar patrons age 21 and older.

Estimated Number of Respondents: 18,000 telephone interviews and 6,000 bar patron interviews.

Estimated Time per Response: 10 minutes per interview.

Total Estimated Annual Burden Hours: 4,000 hours.

Frequency of Collection: There will be three survey waves at each of the five community sites. A telephone survey and bar survey will be conducted during each survey wave, with each respondent interviewed once. The bar interview will be split such that questions will be asked of each respondent both during entry and exit from the bar.

Abstract: Highly visible enforcement (HVE) has had the strongest support in the research literature for effectiveness in reducing alcohol-impaired driving. The unknown at this time is the relationship of the amount of HVE to perceived risk within a community of an alcohol-impaired driver being stopped by law enforcement. In particular, does the perceived risk increase as the amount of HVE increases? And is the optimum effect on awareness and perceived risk achieved through an integrated program where

HVE is integrated into regular law enforcement operations? NHTSA proposes to answer those questions by selecting community sites engaging in different levels of HVE activity during a one-year period, and monitoring community awareness of those enforcement programs and the perceived risk of an alcohol-impaired driver being stopped by law enforcement. Five sites will be selected encompassing integrated, intermediate, and more limited HVE programs.

Data collection to assess program awareness and perceived risk will be of two forms. Telephone surveys will be conducted in each community at three different points in time during the one-year program period. The telephone survey wave in each community will be composed of 1,200 completed interviews with drivers age 18 and older who have consumed alcohol in the past year.

The second form of data collection will be in-person interviews with bar patrons. The intent here is to collect information on program awareness and perceived risk from a population with a heavier concentration of individuals at-risk of driving at illegal blood alcohol concentrations (BACs) than one would find in a community-wide survey. The bar surveys will be conducted during the same times of the year as the telephone surveys. Four hundred bar patrons will be interviewed per community per survey wave. Respondents will be asked a few questions both upon entry and exit from the bar. Breath samples will also be taken in order to correlate BAC with awareness and perceived risk. The breath test results will not be available on-site but will be downloaded later.

In conducting the telephone interviews, the interviewers would use computer-assisted telephone interviewing to reduce interview length and minimize recording errors. No personal information will be collected that would allow any respondent to be identified. The data collection at bars would be anonymous; no personal information that would allow anyone to identify respondents will be collected.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: Desk Officer for Department of Transportation, National Highway Traffic Safety Administration, or by email at *oira_submission@omb.eop.gov,* or fax: 202–395–5806.

Comments Are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department of Transportation, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is most effective if OMB receives it within 30 days of publication of this notice.

Authority: 44 U.S.C. Section 3506(c)(2)(A)

Dated: Issued in Washington, DC, on May 8, 2012.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2012–11392 Filed 5–10–12; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. MCF 21044]

Celerity Partners IV, LLC, Celerity AHI Holdings SPV, LLC, and All Aboard America! Holdings, Inc.—Control—Calco Travel, Inc., Hotard Coaches, Inc., and Industrial Bus Lines, Inc., d/b/a All Aboard America

AGENCY: Surface Transportation Board.

ACTION: Notice Tentatively Approving and Authorizing Transaction.

SUMMARY: All Aboard America! Holdings, Inc. (AHI), Celerity AHI Holdings SPV, LLC (Celerity Holdings), and Celerity Partners IV, LLC (Celerity Partners) (collectively, Applicants) have filed an application under 49 U.S.C. 14303 for their acquisition of control of Calco Travel, Inc. (Calco), Hotard Coaches, Inc. (Coaches), and Industrial Bus Lines, Inc., d/b/a All Aboard America! (Industrial) (collectively, the Three Carriers). The Board is tentatively approving and authorizing the transaction, and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules under 49 CFR 1182.5 and 1182.8.

DATES: Comments must be filed by June 25, 2012. Applicants may file a reply by July 10, 2012. If no comments are filed by June 25, 2012, this notice shall be effective on that date.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MCF 21044 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send one copy of comments to Applicants' representative: Mark J. Andrews, Strasburger & Price, LLP, Suite 640, 1700 K Street NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Amy C. Ziehm, (202) 245–0391. Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.

SUPPLEMENTARY INFORMATION: AHI is a noncarrier corporation established under the laws of Delaware. The majority of AHI's stock is held by a group of investors participating in Celerity Holdings, a noncarrier limited liability company organized under the laws of Delaware. Celerity Partners, the managing member of Celerity Holdings, is also a noncarrier limited liability company organized under the laws of Delaware.

Calco and Coaches are corporations established under the laws of Louisiana, are headquartered in Geismar and New Orleans, La., respectively, and are commonly controlled by Callen Hotard, a noncarrier individual. Mr. Hotard is president of both Calco and Coaches and is the direct owner of 100 percent of the stock of Calco. He and Coleen Hotard are equal co-owners of Hotard Travel, an intermediate holding company and noncarrier, which owns 100 percent of the stock of Coaches. Calco and Coaches hold authority from the Federal Motor Carrier Safety Administration (FMCSA) as motor carriers of passengers (license nos. MC–161177 and MC–143881, respectively). Industrial is a corporation established under the laws of New Mexico, headquartered in Mesa, Ariz., and is controlled through stock ownership by Jack D. Wigley, a noncarrier individual, and by the Wigley family trusts (Wigley Trusts), which are also noncarriers. Industrial holds a FMCSA license (MC–133171) as a motor carrier of passengers.

Calco and Coaches currently operate a total of 89 vehicles in Louisiana and Mississippi. According to Applicants, Calco and Coaches have been operationally integrated to a significant degree since coming under common control of Mr. Hotard.[1] Applicants state that charter and sightseeing services account for approximately 67 percent of the combined Calco-Coaches revenues, with contracted transit and shuttle services accounting for the remaining 33 percent. Industrial operates 84 vehicles

[1] *See Callen Hotard—Acquis.—Hotard Coaches, Inc.,* MCF 21022 (STB served July 13, 2007).

in Arizona, New Mexico, and Texas. Applicants indicate that 38 percent of Industrial's revenues are derived from charter and sightseeing services and 51 percent of its revenues come from contracted transit and shuttle work. The remaining 11 percent of Industrial's revenues, according to Applicants, come from scheduled regular-route operations and related package express service and vehicle maintenance and repair services for third parties.

Under the proposed transaction, Applicants seek permission for AHI (and for Celerity Partners and Celerity Holdings indirectly) to acquire 100 percent control of Calco through purchase of its stock from Mr. Hotard, of Coaches through purchase of its stock from Hotard Travel, and of Industrial through purchase of its stock from Mr. Wigley and Wigley Trusts. Applicants state that the acquisition would be structured through a series of stock purchase agreements (SPAs), to be executed by and between the Applicants and the selling shareholders of each of the Three Carriers, and that Mr. Hotard and Mr. Wigley would become minority shareholders in AHI. The parties state that they anticipate that the SPAs will be executed during April 2012.[2]

Under 49 U.S.C. 14303(b), the Board must approve and authorize a motor carrier of passengers transaction it finds consistent with the public interest, taking into consideration at least: (1) The effect of the transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees. Applicants submitted information, as required by 49 CFR 1182.2, including the information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that the 12-month aggregate gross operating revenues of the Three Carriers exceeded $2 million.

Applicants state that the proposed transaction will have no significant impact on the adequacy of transportation services available to the public, because Applicants do not intend to change substantially the physical operations historically conducted by the Three Carriers. Rather, Applicants anticipate enhancing operations of the Three Carriers by implementing vehicle sharing arrangements, by providing coordinated driver training and safety management services, and by centralizing various management support functions. With respect to fixed charges, Applicants state that their control of the Three Carriers would generate economies of scale that would reduce a variety of unit costs and that, with its increased market position, Applicants would be able to access financing on more favorable terms. In addition to better interest rates, Applicants expect that the Three Carriers would be able to enhance modestly their volume purchasing power, thus reducing insurance premiums and achieve deeper volume discounts for equipment and fuel. According to Applicants, the transaction would have a positive impact on employee interests, as the economies and efficiencies resulting from the proposed transaction would directly benefit the Three Carriers' employees by maintaining job security and retaining or expanding the volume of available work.

Applicants further note that the acquisition would have no adverse impact on competition, namely because Industrial competes in a geographic market that does not significantly overlap the geographic market in which Calco and Coaches compete. Applicants also state that the Three Carriers face significant competition in both commuter and shuttle services under contract, as well as charter or leisure transportation in motor coaches. Additional information, including a copy of the application, may be obtained from Applicants' representative.

On the basis of the application, the Board finds that the proposed acquisition of control is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, this finding will be vacated automatically, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

The party's application and Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed as having been vacated.

3. This notice will be effective June 25, 2012, unless opposing comments are timely filed by June 25, 2012.

4. A copy of this decision will be served on: (1) U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590.

Decided: May 3, 2012.

By the Board, Chairman Elliott, Vice Chairman Mulvey, and Commissioner Begeman.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2012–11389 Filed 5–10–12; 8:45 am]

BILLING CODE 4915–01–P

[2] We note that Applicants may not exercise control over the Three Carriers until Board approval and authorization are effective.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35619]

Tennessee Southern Railroad Company, Patriot Rail, LLC, Patriot Rail Holdings LLC, and Patriot Rail Corp.—Continuance in Control Exemption—Kingman Terminal Railroad, LLC

Tennessee Southern Railroad Company (TSRR), Patriot Rail, LLC (PRL), and its subsidiaries Patriot Rail Holdings LLC (PRH) and Patriot Rail Corp. (Patriot) (collectively, the parties) have filed a verified notice of exemption under 49 CFR 180.2(d)(2) to continue in control of Kingman Terminal Railroad, LLC (KTRR) upon KTRR's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in *Kingman Terminal Railroad, LLC—Operation Exemption—Kingman Airport Authority, Inc.,* Docket No. FD 35618, wherein KTRR seeks Board approval to operate over approximately 3 miles of track within the Kingman Airport & Industrial Park, in Mohave County, Ariz.

The parties intend to consummate the transaction on or after May 27, 2012, the effective date of the exemption (30 days after the notice of exemption was filed).

TSRR is a rail carrier. PRL, PRH, and Patriot are noncarriers that control the following 13 Class III rail carriers: TSRR; Rarus Railway Company; Utah Central Railway Company, Sacramento Valley Railroad, Inc.; The Louisiana and North West Railroad Company LLC;

Temple & Central Texas Railway, Inc.; Piedmont & Northern Railway, Inc.; Columbia & Cowlitz Railway, LLC; DeQueen and Eastern Railroad, LLC; Golden Triangle Railroad, LLC; Patriot Woods Railroad, LLC; Texas, Oklahoma & Eastern Railroad, LLC; and Mississippi & Skuna Valley Railroad, LLC.

The parties represent that: (1) The rail line to be operated by KTRR will not connect with any of the subsidiary railroads of TSRR, PRL, PRH, and Patriot; (2) the continuance in control of KTRR is not intended to connect with any railroads in the corporate family of TSRR, PRL, PRH, and Patriot; (3) the transaction does not involve a Class I rail carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

The parties state that the purpose of the proposed transaction is to enable PRL, PRH, and Patriot to use their management's experience and expertise in operating short line railroads and their financial resources to provide efficient and effective rail freight service to the Kingman Airport & Industrial Park and to create a financially viable railroad in KTRR.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than May 18, 2012 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35619, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Louis E. Gitomer, Law Offices of Louis E. Gitomer LLC, 600 Baltimore Avenue, Suite 301, Towson, MD 21204.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: May 8, 2012.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. White,

Clearance Clerk.

[FR Doc. 2012–11443 Filed 5–10–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35620]

Columbus & Chattahoochee Railroad, Inc.—Lease and Operation Exemption—Norfolk Southern Railway Company

Columbus & Chattahoochee Railroad, Inc. (CCR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to lease from Norfolk Southern Railway Company (NSR) and operate 25.50 miles of rail line consisting of two segments: (1) Between milepost S 292.8 near Girard, Ala., and milepost S 303.9 near Nuckols, Ala., a distance of 11.10 miles; and (2) between milepost NU 0 near Nuckols and milepost NU 14.4 near Mahrt, Ala., a distance of 14.40 miles (collectively, the line). This transaction is related to a concurrently filed petition for exemption in *Genesee & Wyoming Inc.—Continuance in Control Exemption—Columbus & Chattahoochee Railroad, Inc.,* Docket No. FD 35621, in which Genesee & Wyoming Inc. (GWI), a noncarrier, seeks Board approval to continue in control of CCR upon CCR's becoming a Class III carrier.

As a result of this transaction, and pursuant to a lease agreement dated April 26, 2012, CCR will provide freight rail service over the line, connecting with and interchanging traffic with NSR at NSR's Columbus Yard in Columbus, Ga. The line will connect indirectly with Georgia Southwestern Railroad, Inc. (GSWR), a Class III carrier also controlled by GWI, at Columbus Yard. CCR states that there are no interchange commitments to NSR as part of this transaction.

CCR states that it plans to commence operations on July 1, 2012, more than 30 days after the filing of the notice of exemption.

CCR certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier. Because CCR's projected annual revenues after the transaction will exceed $5 million, CCR certified to the Board on April 30, 2012, that it had complied with the requirements of 49 CFR 1150.32(e) by providing notice to employees and their labor unions on the affected 25.50 miles of rail line. Under 49 CFR 1150.32(e), this exemption cannot become effective until 60 days after the date notice was provided, which would be June 29, 2012.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than June 22, 2012 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35620, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Eric M. Hocky, Thorp Reed & Armstrong, LLP, One Commerce Square, 2005 Market Street, Suite 1000, Philadelphia, PA 19103.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: May 8, 2012.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2012–11411 Filed 5–10–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35618]

Kingman Terminal Railroad, LLC—Operation Exemption—Kingman Airport Authority, Inc.

Kingman Terminal Railroad, LLC (KTRR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to operate over approximately 3 miles of track [1] within the Kingman Airport & Industrial Park, in Mohave County, Ariz. (the Line).[2] According to KTRR, the Line has been operated as excepted track by BNSF Railway Company (BNSF). KTRR states that BNSF is voluntarily terminating its switching operation on the Line. KTRR

[1] KTRR states that there are no mileposts on the Line.

[2] KTRR has filed a copy of the Railroad Lease and Operating Agreement that KTRR has entered into with the Kingman Airport Authority, Inc., a noncarrier. *See Anthony Macrie—Continuance in Control Exemption—N.J. Seashore Lines, Inc.,* FD 35296, slip op. at 3–4 (STB served Aug. 31, 2010).

intends to interchange traffic with BNSF.

This transaction is related to a concurrently filed verified notice of exemption in *Tennessee Southern Railroad Company, Patriot Rail, LLC, Patriot Rail Holdings LLC, and Patriot Rail Corp.—Continuance in Control Exemption—Kingman Terminal Railroad, LLC,* Docket No. FD 35619, wherein Tennessee Southern Railroad Company, Patriot Rail, LLC, and its subsidiaries Patriot Rail Holdings LLC and Patriot Rail Corp., seek Board approval to continue in control of KTRR upon KTRR's becoming a Class III rail carrier.

According to KTRR, the transaction is expected to be consummated on or after May 27, 2012, the effective date of the exemption (30 days after the notice of exemption was filed).

KTRR certifies that its projected annual revenues as a result of this transaction will not exceed those that would make it a Class III carrier and would not exceed $5 million.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than May 18, 2012 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35618, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Louis E. Gitomer, Law Offices of Louis E. Gitomer LLC, 600 Baltimore Avenue, Suite 301, Towson, MD 21204.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: May 8, 2012.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. White,

Clearance Clerk.

[FR Doc. 2012–11440 Filed 5–10–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Renewal of a Currently Approved Collection; Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC).

ACTION: Notice and request for comments.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The OCC is soliciting comments concerning the currently approved Minimum Security Devices and Procedures, Reports of Suspicious Activities, and Bank Secrecy Act Compliance Program information collection, which is being renewed without change.

DATES: Written comments should be received on or before July 10, 2012.

ADDRESSES: Interested parties are invited to submit written comments to the OCC. All comments should refer to the Office of Management and Budget (OMB) control numbers. Direct all written comments as follows:

Communications Division, Office of the Comptroller of the Currency, Public Information Room, Mailstop 2–3, Attention: 1557–0180, 250 E Street SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–5274, or by electronic mail to *regs.comments@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC's Public Information Room, 250 E Street SW., Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–4700. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

Additionally, you should send a copy of your comments to OCC Desk Officer, 1557–0180, by mail to U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: You can request additional information or a copy of the collection from Mary H. Gottlieb, OCC Clearance Officer, (202) 874–5090, Office of the Comptroller of the Currency, 250 E Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION:

The OCC is renewing without change all information collections covered under the information collection titled: ''Minimum Security Devices and Procedures, Reports of Suspicious Activities, and Bank Secrecy Act Compliance.''

Title: Minimum Security Devices and Procedures, Reports of Suspicious Activities, and Bank Secrecy Act Compliance program.

OMB Control No.: 1557–0180.

Form Numbers: 8010–1/8010–9.

Abstract: In 1985, the bank supervisory agencies (Agencies),[1] issued procedures to be used by banks and certain other financial institutions operating in the United States to report known or suspected criminal activities to the appropriate law enforcement and Banking Supervisory Agencies. Beginning in 1994, the Agencies and the Financial Crimes Enforcement Network (FinCEN) undertook a redesign of the reporting process and developed the Suspicious Activity Report, which became effective in April 1996. The report is authorized by the following regulations: 31 CFR 103.18 (FinCEN); 12 CFR 21.11 and 12 CFR 163.180 (OCC); 12 CFR 208.62(c), 211.5(k), 211.24(f), and 225.4(f) (Board); 12 CFR 353.3 (FDIC); 12 CFR 748.1 (NCUA). The regulations were issued under the authority contained in the following statutes: 31 U.S.C. 5318(g) (FinCEN); 12 U.S.C. 93a, 1463, 1464, 1818, 1881–84, 3401–22, 31 U.S.C. 5318 (OCC); 12 U.S.C. 248(a)(1), 625, 1818, 1844(c), 3105(c)(2) and 3106(a) (Board); 12 U.S.C1818–1820 (FDIC); 12 U.S.C. 1766(a), 1789(a) (NCUA).

Current Action: The OCC proposes to renew, without revision, the currently approved collection.

Type of Review: Regular.

Affected Public: Business, for-profit institutions, and non-profit institutions.

Estimated Number of Respondents: 2,021.

Estimated Total Annual Responses: 424,410.

Estimated Burden per Response: 1 hour per form.

Estimated Total Annual Burden: 548,560 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information

[1] The Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the National Credit Union Administration.

displays a valid Office of Management and Budget control number. Records required to be retained under the Bank Secrecy Act and these regulations issued by the Banking Supervisory Agencies must be retained for five years. Generally, information collected pursuant to the Bank Secrecy Act is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information shall have practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology, and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 8, 2012.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. 2012–11417 Filed 5–10–12; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs.

ACTION: Notice of New System of Records ''Virtual Lifetime Electronic Record (VLER)-VA'' (168VA10P2).

SUMMARY: The Privacy Act of 1974 (5 U.S.C. 552(e)(4)) requires that all agencies publish in the **Federal Register** a notice of the existence and character of their systems of records. Notice is hereby given that the Department of Veterans Affairs (VA) is establishing a new system of records entitled ''Virtual Lifetime Electronic Record (VLER)–VA'' (168VA10P2).

DATES: Comments on this new system of records must be received no later than June 11, 2012. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by the VA, the new system will become effective June 11, 2012.

ADDRESSES: Written comments concerning the proposed amended system of records may be submitted through *www.regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Veterans Health Administration (VHA) Privacy Officer, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, telephone (704) 245–2492.

SUPPLEMENTARY INFORMATION:

I. Description of Proposed Systems of Records

Background

The Virtual Lifetime Electronic Record (VLER) is an overarching program being developed by the Department of Veterans Affairs (VA) as a result of President Obama's direction on April 9, 2009, to the VA and the Department of Defense (DoD) to create the VLER, which will allow the electronic sharing with VA, DoD and NwHIN participants. The purpose of use will include, but not limited to healthcare treatment information, disability adjudication, and benefits.

For this proposed system of records the individuals covered by the system include Veterans and their family members or caregivers; members of the Armed Services, Reserves or National Guard; and VA employees who access information through VLER.

The proposed system of records contains patient demographic information (*e.g.,* name, address, phone numbers, date of birth, social security number, internal control number); patient demographic and health information from external health care providers (*e.g.,* medication listing allergies, consultations and referrals, progress notes, history and physicals, discharge summaries, diagnostic studies and procedure notes, Advanced Directives, problem lists, laboratory reports, lists of procedures and encounters); benefits information (*e.g.,* disability rating, service connection rating); and information on Veterans' preferences for restricting the sharing of their health information (*e.g.,* authorizations, restriction requests, revocation of authorizations). The records include information provided by Veterans and their family members or caregivers, members of the Armed Services, Reserves or National Guard, and VA employees; and information from VA computer systems and databases including, but not limited to, Veterans Health Information Systems and Technology Architecture (VistA)-VA (79VA19) and National Patient Databases-VA (121VA19), VA Medical Centers (VAMC), federal and non-federal VLER/NwHIN partners and the Department of Defense.

The purpose of the system of records is to provide a repository for the clinical and administrative information that is used to accomplish the purposes described. The purpose of use will include, but not be limited to, health care treatment information, disability adjudication, and benefits to the Veteran both within the VA Medical Center and in sharing with partners who are participating through the Nationwide Health Information Network (NwHIN) in the VLER pilots and subsequent national roll-out. Data stored in the VLER Veterans Authorizations and Preferences (VAP) system is used to prepare various management, tracking and follow-up reports that are used to assist in the management and operation of the health care facility, and the planning and delivery of patient medical care. Data may be used to track and evaluate patient care services, the distribution and utilization of resources, and the performance of vendors and employees. The data may also be used for such purposes as scheduling patient treatment services, including nursing care, clinic appointments, survey, diagnostic and therapeutic procedures. Data may also be used to track the ordering, delivery, maintenance and repair of equipment, and for follow-up activities to determine if the actions were accomplished and to evaluate the results.

II. Proposed Routine Use Disclosures of Data in the System

To the extent that records contained in the system include information protected by 45 CFR parts 160 and 164, i.e., individually identifiable health information, and 38 U.S.C. 7332, i.e., medical treatment information related to

drug abuse, alcoholism or alcohol abuse, sickle cell anemia, or infection with the human immunodeficiency virus, that information cannot be disclosed under a routine use unless there is also specific statutory authority in 38 U.S.C. 7332 and regulatory authority in 45 CFR parts 160 and 164 permitting disclosure.

VHA is proposing the following routine use disclosures of information to be maintained in the system:

1. On its own initiative, the VA may disclose information, except for the names and home addresses of veterans and their dependents, to a Federal, State, local, tribal or foreign agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto. On its own initiative, the VA may also disclose the names and addresses of veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto. VA must be able to comply with the requirements of agencies charged with enforcing the law and conducting investigations. VA must also be able to provide information to State or local agencies charged with protecting the public's health as set forth in State law.

2. Disclosure may be made to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and to identify the type of information requested), when necessary to obtain information relevant to an individual's eligibility, care history, or other benefits.

3. Disclosure of information to a NwHIN participant for the purpose of providing care or treatment to VA patients, reimbursement for health care services, or determining eligibility for disability benefits.

4. The record of an individual who is covered by a system of records may be disclosed to a Member of Congress, or a staff person acting for the Member, when the Member or staff person requests the record on behalf of and at the written request of the individual. Individuals sometimes request the help of a member of Congress in resolving some issues relating to a matter before the VA. The member of Congress then writes to the VA, and the VA must be able to give sufficient information to give a response to the inquiry.

5. Disclosure may be made to National Archives and Records Administration (NARA) and the General Services Administration (GSA) in records management inspections conducted under authority of Title 44, Chapter 29, of the United States Code (U.S.C). NARA and GSA are responsible for management of old records no longer actively used, but which may be appropriate for preservation, and for the physical maintenance of the Federal government's records. VA must be able to provide the records to NARA and GSA in order to determine the proper disposition of such records.

6. VA may disclose information from this system of records to the Department of Justice (DoJ), either on VA's initiative or in response to DoJ's request for the information, after either VA or DoJ determines that such information is relevant to DoJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that release of the records to the DoJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its own initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

7. Disclosure may be made to a national certifying body which has the authority to make decisions concerning the issuance, retention or revocation of licenses, certifications or registrations required to practice a health care profession, when requested in writing by an investigator or supervisory official of the national certifying body for the purpose of making a decision concerning the issuance, retention or revocation of the license, certification or registration of a named health care professional. VA must be able to report information regarding the health information a health care practitioner knew about or had access to when making care decisions to a national certifying body charged with maintaining the health and safety of patients by making a decision about a health care professional's license, certification or registration, such as issuance, retention, revocation or other actions such as suspension.

8. VA may disclose information to officials of the Merit Systems Protection Board MSPB), or the Office of Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions, promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

9. VA may disclose information to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or for other functions of the Commission as authorized by law or regulation. VA must be able to provide information to the Commission to assist it in fulfilling its duties to protect employee's rights, as required by statute and regulation.

10. VA may disclose to the Fair Labor Relations Authority (FLRA) (including its General Counsel) information related to the establishment of jurisdiction, the investigation and resolution of allegations of unfair labor practices, or information in connection with the resolution of exceptions to arbitration awards when a question of material fact is raised; to disclose information in matters properly before the Federal Services Impasse Panel, and to investigate representation petitions and conduct or supervise representation elections. VA must be able to provide information to FLRA to comply with the statutory mandate under which it operates.

11. Disclosures of relevant information may be made to individuals, organizations, private or public agencies, or other entities with whom VA has a contract or agreement or where there is a subcontract to perform the services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement. This routine use includes disclosures by the individual or entity performing the service for VA to any secondary entity or individual to perform an activity that is necessary for individuals, organizations, private or public agencies, or other entities or individuals with whom VA has a contract or agreement to provide the service to VA.

12. Disclosure to other Federal agencies may be made to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

13. VA may, on its own initiative, disclose any information or records to appropriate agencies, entities, and persons when (1) VA suspects or has

confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise, there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by the Department or another agency or disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by the Department to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724, as the terms are defined in 38 U.S.C. 5727.

14. VA may disclose information from this system to a Federal agency for the purpose of conducting research and data analysis to perform a statutory purpose of that Federal agency upon the prior written request of that agency, provided that there is legal authority under all applicable confidentiality statutes and regulations to provide the data and VA has determined prior to the disclosure that the VA data handling requirements are satisfied. The purpose of this disclosure is to aid other Federal agency conduct of government research to accomplish a statutory purpose of that agency.

III. Compatibility of the Proposed Routine Uses

The Privacy Act permits the VA to disclose information about individuals without their consent for a routine use when the information will be used for a purpose that is compatible with the purpose for which the VA collected the information. In all of the routine use disclosures described above, either the recipient of the information will use the information in connection with a matter relating to one of VA's programs, will use the information to provide a benefit to the VA, or disclosure is required by law.

The notice of intent to publish and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Approved: April 23, 2012.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

SOR #168VA10P2

SYSTEM NAME:

Virtual Lifetime Electronic Record (VLER).

SYSTEM LOCATION:

Records are maintained at Department of Veterans Affairs (VA), Austin Information Technology Center (AITC), 1615 Woodward Street, Austin, TX 78772.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records contain information on Veterans and the family members or caregivers; members of the armed services, Reserves or National Guard; and VA employees who access information through VLER.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may include patient demographic information (*e.g.,* name, address, phone numbers, date of birth, social security number); patient demographic and health information from external health care providers (*e.g.,* medication listing allergies, consultations and referrals, history and physicals, discharge summaries, diagnostic studies and procedure notes, Advanced Directives, problem lists, laboratory reports, lists of procedures and encounters); benefits information (*e.g.,* disability rating, service connection rating); and information on Veterans' preferences for restricting the sharing of their health information (*e.g.,* authorizations, restriction requests, revocation of authorizations).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Section 501.

PURPOSE (S):

The records and information may be used for the ongoing communication of current healthcare data among VLER/Nationwide Health Information Network (NwHIN) partners, Department of Defense (DoD) and VA to promote improved quality of patient care, reduce duplicative ordering of tests, services and pharmaceuticals; for statistical analysis to produce various management, workload tracking, and follow-up reports; to track and evaluate the ordering and delivery of equipment, services and patient care; for the planning, distribution and utilization of resources; to monitor the performance of Veterans Integrated Service Networks (VISN); and to allocate clinical and administrative support to patient to include but not limited to Healthcare treatment, disability adjudication, and benefits.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To the extent that records contained in the system include information protected by 38 U.S.C. 7332, i.e., medical treatment information related to drug abuse, alcoholism or alcohol abuse, sickle cell anemia or infection with the human immunodeficiency virus, that information cannot be disclosed under a routine use unless there is also specific statutory authority permitting disclosure.

VA may disclose protected health information pursuant to the following routine uses where required by law, or required or permitted by 45 CFR Parts 160 and 164.

1. On its own initiative, the VA may disclose information, except for the names and home addresses of veterans and their dependents, to a Federal, State, local, tribal or foreign agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto.

2. Disclosure may be made to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and to identify the type of information requested), when necessary to obtain information relevant to an individual's eligibility, care history, or other benefits.

3. Disclosure of information to a NwHIN participant for the purpose of providing care or treatment to VA patients, reimbursement for health care services, or determining eligibility for government disability benefits.

4. The record of an individual who is covered by a system of records may be disclosed to a Member of Congress, or a staff person acting for the Member, when the Member or staff person requests the record on behalf of and at the written request of the individual.

5. Disclosure may be made to National Archives and Records Administration (NARA) and the General Services Administration (GSA) in records management inspections conducted under authority of Title 44, Chapter 29, of the United States Code (U.S.C.).

6. VA may disclose information from this system of records to the Department

of Justice (DoJ), either on VA's initiative or in response to DoJ's request for the information, after either VA or DoJ determines that such information is relevant to DoJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that release of the records to the DoJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its own initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

7. Disclosure may be made to a national certifying body which has the authority to make decisions concerning the issuance, retention or revocation of licenses, certifications or registrations required to practice a health care profession, when requested in writing by an investigator or supervisory official of the national certifying body for the purpose of making a decision concerning the issuance, retention or revocation of the license, certification or registration of a named health care professional.

8. VA may disclose information to officials of the Merit Systems Protection Board MSPB), or the Office of Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions, promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

9. VA may disclose information to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or for other functions of the Commission as authorized by law or regulation.

10. VA may disclose to the Fair Labor Relations Authority (FLRA) (including its General Counsel) information related to the establishment of jurisdiction, the investigation and resolution of allegations of unfair labor practices, or information in connection with the resolution of exceptions to arbitration awards when a question of material fact is raised; to disclose information in matters properly before the Federal Services Impasse Panel, and to investigate representation petitions and conduct or supervise representation elections.

11. Disclosures of relevant information may be made to individuals, organizations, private or public agencies, or other entities with whom VA has a contract or agreement or where there is a subcontract to perform the services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

12. Disclosure to other Federal agencies may be made to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

13. VA may, on its own initiative, disclose any information or records to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise, there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by the Department or another agency or disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by the Department to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724, as the terms are defined in 38 U.S.C. 5727.

14. VA may disclose information from this system to a Federal agency for the purpose of conducting research and data analysis to perform a statutory purpose of that Federal agency upon the prior written request of that agency, provided that there is legal authority under all applicable confidentiality statutes and regulations to provide the data and VA has determined prior to the disclosure that the VA data handling requirements are satisfied.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic storage media including magnetic tape, disk, laser optical media.

RETRIEVABILITY:

Records are retrieved by name, social security number or other assigned identifiers of the individuals on whom they are maintained. For reporting purposes records can also be retrieved by Internal Control Number (ICN), date of service or access by providers, facility, and by organizational user name.

SAFEGUARDS:

1. Access to and use of national administrative databases, warehouses, and data marts are limited to those persons whose official duties require such access, and the VA has established security procedures to ensure that access is appropriately limited. Information security officers and system data stewards review and authorize data access requests. VA regulates data access with security software that authenticates users and requires individually unique codes and passwords. VA provides information security training to all staff and instructs staff on the responsibility each person has for safeguarding data confidentiality.

2. Physical access to computer rooms housing national administrative databases, warehouses, and data marts is restricted to authorized staff and protected by a variety of security devices. Unauthorized employees, contractors, and other staff are not allowed in computer rooms. The Federal Protective Service or other security personnel provide physical security for the buildings housing computer rooms and data centers.

3. Data transmissions between operational systems and national administrative databases, warehouses, and data marts maintained by this system of record are protected by state of the art telecommunication software and hardware. This may include firewalls, intrusion detection devices, encryption, and other security measures necessary to safeguard data as it travels across the VA Wide Area Network.

4. In most cases, copies of back-up computer files are maintained at off-site locations.

RETENTION AND DISPOSAL:

In accordance with the records disposition authority approved by the Archivist of the United States, health

information stored on electronic media storage is maintained for seventy-five (75) years after the last episode of patient care and then deleted.

SYSTEM MANAGER (S) AND ADDRESS:

Official maintaining this system of records and responsible for policies and procedures is Director Standards and Interoperability, Chief Health Informatics Office/Office of Informatics and Analytics/Veterans Health Information, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

NOTIFICATION PROCEDURE:

Individuals who wish to determine whether this system of records contains information about them should contact their closest VA Medical Center (VAMC). Inquiries should include the person's full name, social security number, location and dates of treatment or location and dates of employment and their return address.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of records in this system may write the Director Standards and Interoperability, Chief Health Informatics Office/Office of Informatics and Analytics/Veterans Health Information, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

CONTESTING RECORD PROCEDURES:

(See Record Access Procedures above.)

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by Veterans and their family members or caregivers, members of the Armed Services, Reserves or National Guard, VA employees, VA computer systems, Veterans Health Information Systems and Technology Architecture (VistA)-VA (79VA19), National Patient Databases-VA (121VA19), Patient Medical Record—VA (24VA19), federal and non-federal VLER/NwHIN partners and Department of Defense.

[FR Doc. 2012–11485 Filed 5–10–12; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Amendment of System of Records ''National Patient Databases-VA'' (121VA19).

SUMMARY: As required by the Privacy Act of 1974 (5 U.S.C. 552a(e)(4)), notice is hereby given that the Department of Veterans Affairs (VA) is amending the system of records entitled ''National Patient Databases-VA'' (121VA19) as set forth in 75 FR 72873. VA is amending the system of records by revising the System Number, Categories of Records in the System, Purposes, Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses, and Appendix 4. VA is republishing the system notice in its entirety.

DATES: Comments on this new system of records must be received no later than June 11, 2012. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the new system will become effective June 11, 2012.

ADDRESSES: Written comments concerning the proposed new system of records may be submitted through *www.regulations.gov;* by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online through the FDMS) at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Stephania H. Griffin, Veterans Health Administration (VHA) Privacy Officer, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, telephone (704) 245–2492.

SUPPLEMENTARY INFORMATION:

Background: VHA is the largest health care provider in the country. VHA collects health care information from its local facilities to evaluate quality of services, clinical resource utilization, and patient safety, as well as to distribute medical information, such as alerts or recalls, track specific diseases, and monitor patients. National-level information is also needed for other activities, such as medical research and the development of National Best Clinical Practice Guidelines and National Quality Standards. VHA gathers this information from a wide variety of sources, including directly from Veterans; from information systems located at VHA medical centers, Veterans Integrated Service Networks (VISNs), other VHA facilities, such as the Health Eligibility Center; and Federal departments and agencies such as the U.S. Department of Defense (DoD) and the Food and Drug Administration. As the data is collected, VHA stores it in several national patient databases.

The system number is changed from 121VA19 to 121VA10P2 to reflect the current organizational alignment.

The Category of Records in the System is amended to reflect the data collected by VHA Homeless Programs Office of information about homeless Veterans who receive services provided by VA administered programs, as well as services provided by external Federal agencies, and other private and public entities. Homeless data includes any patient-level records created by the Northeast Program Evaluation Center (NEPEC) and homeless data from U.S. Department of Housing and Urban Development (HUD) Homeless Management Information System (HMIS), Health and Human Services, Department of Labor, Social Security Administration, DoD to include Defense Enrollment Eligibility Reporting System (DEERS), Transitional Assessment Program (TAP), Post Deployment Health Assessment (PDHA), National Death Index (NDI) from the Centers for Disease Control, and Department of Justice (DoJ) information. Data will include information from the following programs: Online Data Collection (ODC) system supported by NEPEC and VHA Support Services Center (VSSC) to include electronic information from all homeless programs, i.e. Health care for Homeless Veterans (HCHV) Program, Grant and Per Diem (GPD) Program, HUD–Veterans Affairs Supported Housing (HUD–VASH), Domiciliary Care for Homeless Veterans (DCHV) Program, Healthcare for Re-entry Veterans (HCRV) Program, Veterans Justice Outreach (VJO) Program, Homeless Veteran Dental Initiative, Community Homelessness Assessment, Local Education, and Networking Groups (CHALENG), Compensated Work Therapy (CWT), HUD/VA Prevention pilot, and Supportive Services for Veterans and Families (SSVF). This information is collected so that PCS can support frontline staff with screening and case management of homeless Veterans and Veterans at risk for homelessness, collection of baseline, periodic updates and information about final disposition following completion of VHA homeless programs and services and to create a single registry of information about homeless Veterans from all available sources in order to

provide periodic reports and/or extracts/updates that will flow externally to other agencies and organizations as well as internal stakeholders. Also, The Categories of Records in the System is being amended to add clinically oriented information associated with My HealtheVet such as secure messages.

The Purpose in this system of records is being amended to reflect that the homelessness records and information will be used for statistical analysis to produce various management, workload tracking, and follow-up reports; to track and evaluate the goal of ending Veteran homeless. Healthcare Associated Infections and Influenza Surveillance System (HAIISS) data will be available to VHA clinicians to use for monitoring of healthcare-associated infections and for transmittal to state/local health departments for biosurveillance purposes.

Routine use two (2) has been amended to add Federal, state or local public health, health care or program benefit agencies that improves the quality and safety of health care for our Veterans.

Routine use three (3) has been amended to add Federal, State and local Government.

The following routine use disclosure statements are added:

Routine use twenty-four (24) states that VA may disclose name(s) and address(es) of present or former members of the armed services and/or their dependents under certain circumstances: (a) To any nonprofit organization, if the release is directly connected with the conduct of programs and the utilization of benefits under Title 38, or (b) to any criminal or civil law enforcement governmental agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of such organization, agency, or instrumentality has made a written request for such name(s) or address(es) for a purpose authorized by law, provided that the records will not be used for any purpose other than that stated in the request and that the organization, agency, or instrumentality is aware of the penalty provision of 38 U.S.C. 5701(f).

Routine use twenty-five (25) states that VA may disclose information, including demographic information, to HUD for the purpose of reducing homelessness among Veterans by implementing the Federal strategic plan to prevent and end homelessness and by evaluating and monitoring the HUD–VASH program.

Appendix 4 has been amended to include Homeless Operational, Management and Evaluation System (HOMES), Homeless Veterans Registry, and Regional Data Warehouses (RDW). Defense and Veterans Eye Injury Registry (DVEIR)-VA Service-Related Eye Injury Data Store and Embedded Fragment Registry (EFR), and Clinical Case Registries (CCR) was removed and are now entered as a single system called Converged Registries Solution. Cardiac Assessment Tracking and Reporting for Cardiac Cauterization Laboratories (CART–CL) was renamed to VA Clinical Assessment Reporting and Tracking (CART) Program. Also, Bidirectional Health Information Exchange (BHIE) and Federal Health Information Exchange (FHIE) are being amended to reflect a change in address to SunGard, 1500 Spring Garden Street, Philadelphia, PA 19130.

The notice of amendment and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Approved: April 23, 2012.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

121VA10P2

SYSTEM NAME:

National Patient Databases-VA.

SYSTEM LOCATION:

Records are maintained at VA medical centers, VA data processing centers, VISNs and Office of Information (OI) field offices. Address location for each VA national patient database is listed in VA Appendix 4 at the end of this document.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records contain information for all individuals (1) receiving health care from VHA, and (2) Providing the health care. Individuals encompass Veterans and their immediate family members, members of the armed services, current and former employees, trainees, contractors, subcontractors, consultants, volunteers, and other individuals working collaboratively with VA.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may include information and health information related to:

1. Patient medical record abstract information, but not limited to, including information from Patient Medical Record—VA (24VA19).

2. Identifying information (e.g., name, birth date, death date, admission date, discharge date, gender, Social Security number, taxpayer identification number); address information (e.g., home and/or mailing address, home telephone number, emergency contact information such as name, address, telephone number, and relationship); prosthetic and sensory aid serial numbers; medical record numbers; integration control numbers; information related to medical examination or treatment (e.g., location of VA medical facility providing examination or treatment, treatment dates, medical conditions treated or noted on examination); information related to military service and status;

3. Medical benefit and eligibility information;

4. Patient workload data such as admissions, discharges, and outpatient visits; resource utilization such as laboratory tests, x-rays;

5. Patient Satisfaction Survey Data which include questions and responses;

6. External Peer Review Program (EPRP) data capture;

7. ODC system supported by NEPEC and VHA VSSC to include electronic information from all Veteran homeless programs and external sources; and

8. Clinically oriented information associated with My HealtheVet such as secure messages.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Section 501.

PURPOSES:

The records and information may be used for statistical analysis to produce various management, workload tracking, and follow-up reports; to track and evaluate the ordering and delivery of equipment, services, and patient care; for the planning, distribution, and utilization of resources; to monitor the performance of VISNs; and to allocate clinical and administrative support to patient medical care. The data may be used for VA's extensive research programs in accordance with VA policy. In addition, the data may be used to assist in workload allocation for patient treatment services including provider panel management, nursing care, clinic appointments, surgery, prescription processing, diagnostic and therapeutic procedures; to plan and schedule training activities for employees; for audits, reviews, and investigations conducted by the network directors office and VA Central Office; for quality assurance audits, reviews, and investigations; for law enforcement investigations; and for personnel

management, evaluation and employee ratings, and performance evaluations. Survey data will be collected for the purpose of measuring and monitoring national, VISN, and facility-level performance on VHA's Veteran Health Care Service Standards (VHSS) pursuant to Executive Order 12862 and VHA Customer Service Standards Directive. The VHSS are designed to measure levels of patient satisfaction in areas that patients have defined as important in receiving quality, patient-centered health care. Results of the survey data analysis are shared throughout the VHA system. The EPRP data are collected in order to provide medical centers and outpatient clinics with diagnosis and procedure-specific quality of care information. EPRP is a contracted review of care, specifically designated to collect data to be used to improve the quality of care. The Veteran Homeless records and information will be used for case management in addition to statistical analysis to produce various management, workload tracking, and follow-up reports; to track and evaluate the goal of ending Veteran homelessness. HAIISS data will be available to VHA clinicians to use for monitoring of health care-associated infections and for transmittal to state/local health departments for biosurveillance purposes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To the extent that records contained in the system include information protected by 38 U.S.C. 7332, i.e., medical treatment information related to drug abuse, alcoholism or alcohol abuse, sickle cell anemia or infection with the human immunodeficiency virus; information protected by 38 U.S.C. 5705, i.e., quality assurance records; or information protected by 45 CFR Parts 160 and 164, i.e., individually identifiable health information, such information cannot be disclosed under a routine use unless there is also specific statutory authority permitting the disclosure. VA may disclose protected health information pursuant to the following routine uses where required or permitted by law.

1. VA may disclose on its own initiative any information in this system, except the names and home addresses of Veterans and their dependents, that is relevant to a suspected or reasonably imminent violation of law, whether civil, criminal, or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, to a Federal, state, local, tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule, or order. On its own initiative, VA may also disclose the names and addresses of Veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal, or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule, or order issued pursuant thereto.

2. Disclosure may be made to any source from which additional information is requested (to the extent necessary to identify the individual, inform the source of the purpose(s) of the request, and identify the type of information requested), when necessary to obtain or provide information relevant to an individual's eligibility, care history, or other benefits across different Federal, state, or local, public health, health care, or program benefit agencies that improves the quality and safety of health care for our Veterans.

3. Disclosure may be made to a Federal agency in the executive, legislative, or judicial branch, State and local Government or the District of Columbia government in response to its request or at the initiation of VA, in connection with disease tracking, patient outcomes, or other health information required for program accountability.

4. Disclosure may be made to the National Archives and Records Administration (NARA) and the General Services Administration (GSA) for records management inspections under authority of Title 44, Chapter 29, of the United States Code.

5. VA may disclose information in this system of records to the DoJ, either on VA's initiative or in response to DoJ's request for the information, after either VA or DoJ determines that such information is relevant to DoJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that disclosure of the records to the DoJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its own initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

6. Records from this system of records may be disclosed to a Federal agency or to a state or local government licensing board and/or to the Federation of State Medical Boards or a similar non-government entity that maintains records concerning individuals' employment histories or concerning the issuance, retention, or revocation of licenses, certifications, or registration necessary to practice an occupation, profession, or specialty, in order for the agency to obtain information relevant to an agency decision concerning the hiring, retention, or termination of an employee.

7. Records from this system of records may be disclosed to inform a Federal agency, licensing boards, or appropriate non-governmental entities about the health care practices of a terminated, resigned, or retired health care employee whose professional health care activity so significantly failed to conform to generally accepted standards of professional medical practice as to raise reasonable concern for the health and safety of patients receiving medical care in the private sector or from another Federal agency.

8. For program review purposes and the seeking of accreditation and/or certification, disclosure may be made to survey teams of the Joint Commission, College of American Pathologists, American Association of Blood Banks, and similar national accreditation agencies or boards with whom VA has a contract or agreement to conduct such reviews but only to the extent that the information is necessary and relevant to the review.

9. Disclosure may be made to a national certifying body that has the authority to make decisions concerning the issuance, retention, or revocation of licenses, certifications, or registrations required to practice a health care profession, when requested in writing by an investigator or supervisory official of the national certifying body for the purpose of making a decision concerning the issuance, retention, or revocation of the license, certification, or registration of a named health care professional.

10. Records from this system that contain information listed in 5 U.S.C. 7114(b)(4) may be disclosed to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions.

11. Disclosure may be made to the representative of an employee of all

notices, determinations, decisions, or other written communications issued to the employee in connection with an examination ordered by VA under medical evaluation (formerly fitness-for duty) examination procedures or Department-filed disability retirement procedures.

12. VA may disclose information to officials of the Merit Systems Protection Board, or the Office of Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions, promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

13. VA may disclose information to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or for other functions of the Commission as authorized by law or regulation.

14. VA may disclose information to the Federal Labor Relations Authority (including its General Counsel) information related to the establishment of jurisdiction, the investigation and resolution of allegations of unfair labor practices, or information in connection with the resolution of exceptions to arbitration awards when a question of material fact is raised; to disclose information in matters properly before the Federal Services Impasses Panel, and to investigate representation petitions and conduct or supervise representation elections.

15. Disclosure of medical record data, excluding name and address, unless name and address are furnished by the requester, may be made to non-Federal research facilities for research purposes determined to be necessary and proper when approved in accordance with VA policy.

16. Disclosure of name(s) and address(s) of present or former personnel of the Armed Services, and/or their dependents, may be made to: (a) A Federal department or agency, at the written request of the head or designee of that agency; or (b) directly to a contractor or subcontractor of a Federal department or agency, for the purpose of conducting Federal research necessary to accomplish a statutory purpose of an agency. When disclosure of this information is made directly to a contractor, VA may impose applicable conditions on the department, agency, and/or contractor to insure the appropriateness of the disclosure to the contractor.

17. Disclosure may be made to individuals, organizations, private or public agencies, or other entities or individuals with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor, subcontractor, public or private agency, or other entity or individual with whom VA has an agreement or contract to perform the services of the contract or agreement. This routine use includes disclosures by the individual or entity performing the service for VA to any secondary entity or individual to perform an activity that is necessary for individuals, organizations, private or public agencies, or other entities or individuals with whom VA has a contract or agreement to provide the service to VA.

18. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

19. VA may disclose information to a Federal agency for the conduct of research and data analysis to perform a statutory purpose of that Federal agency upon the prior written request of that agency, provided that there is legal authority under all applicable confidentiality statutes and regulations to provide the data and the VHA OI has determined prior to the disclosure that VHA data handling requirements are satisfied.

20. Disclosure of limited individual identification information may be made to another Federal agency for the purpose of matching and acquiring information held by that agency for VHA to use for the purposes stated for this system of records.

21. VA may, on its own initiative disclose any information or records to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) VA has determined that as a result of the suspected or confirmed compromise there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by VA or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out VA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by VA to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724, as the terms are defined in 38 U.S.C. 5727.

22. On its own initiative, VA may disclose to the general public via an Internet Web site, Primary Care Management Module (PCMM) information, including the names of its providers, provider panel sizes and reports on provider performance measures of quality when approved in accordance with VA policy.

23. Disclosure to other Federal agencies may be made to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

24. VA may disclose name(s) and address(es) of present or former members of the armed services and/or their dependents under certain circumstances: (a) to any nonprofit organization, if the release is directly connected with the conduct of programs and the utilization of benefits under Title 38, or (b) to any criminal or civil law enforcement governmental agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of such organization, agency, or instrumentality has made a written request for such name(s) or address(es) for a purpose authorized by law, provided that the records will not be used for any purpose other than that stated in the request and that the organization, agency, or instrumentality is aware of the penalty provision of 38 U.S.C. 5701(f).

25. VA may disclose information, including demographic information, to U.S. Department of Housing and Urban Development (HUD) for the purpose of reducing homelessness among Veterans by implementing the Federal strategic plan to prevent and end homelessness and by evaluating and monitoring the HUD-Veterans Affairs Supported Housing (VASH) program.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic storage media including magnetic tape, disk, laser optical media.

RETRIEVABILITY:

Records are retrieved by name, Social Security number, or other assigned

identifiers of the individuals on whom they are maintained.

SAFEGUARDS:

1. Access to and use of national patient databases are limited to those persons whose official duties require such access, and VA has established security procedures to ensure that access is appropriately limited. Information security officers and system data stewards review and authorize data access requests. VA regulates data access with security software that authenticates users and requires individually unique codes and passwords. VA provides information security training to all staff and instructs staff on the responsibility each person has for safeguarding data confidentiality.

2. VA maintains Business Associate Agreements (BAA) and Non-Disclosure Agreements with contracted resources in order to maintain confidentiality of the information.

3. Physical access to computer rooms housing national patient databases is restricted to authorized staff and protected by a variety of security devices. Unauthorized employees, contractors, and other staff are not allowed in computer rooms. The Federal Protective Service or other security personnel provide physical security for the buildings housing computer rooms and data centers.

4. Data transmissions between operational systems and national patient databases maintained by this system of record are protected by state-of-the-art telecommunication software and hardware. This may include firewalls, encryption, and other security measures necessary to safeguard data as it travels across the VA Wide Area Network. Data may be transmitted via a password protected spreadsheet and placed on the secured share point Web portal by the user that has been provided access to their secure file. Data can only be accessed by authorized personnel from each facility within the Polytrauma System of Care and the Physical Medicine and Rehabilitation Program Office.

5. In most cases, copies of back-up computer files are maintained at off-site locations.

RETENTION AND DISPOSAL:

The records are disposed of in accordance with General Records Schedule 20, item 4. Item 4 provides for deletion of data files when the agency determines that the files are no longer needed for administrative, legal, audit, or other operational purposes.

SYSTEMS AND MANAGER(S) AND ADDRESS:

Officials responsible for policies and procedures; Assistant Deputy Under Secretary for Health for Informatics and Analytics (10P2), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420. Officials maintaining this system of records; Director, National Data Systems (10P2C), Austin Automation Center, 1615 Woodward Street, Austin, Texas 78772.

NOTIFICATION PROCEDURE:

Individuals who wish to determine whether this system of records contains information about them should contact the Director of National Data Systems (10P2C), Austin Automation Center, 1615 Woodward Street, Austin, Texas 78772. Inquiries should include the person's full name, Social Security number, location and dates of employment or location and dates of treatment, and their return address.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of records in this system may write or call the Director of National Data Systems (10P2C), Austin Automation Center, 1615 Woodward Street, Austin, Texas 78772, or call the VA Austin Automation Center Help Desk and ask to speak with the VHA Director of National Data Systems at (512) 326–6780.

CONTESTING RECORD PROCEDURES:

(See Record Access Procedures above.)

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by Veterans, VA employees, VA computer systems, Veterans Health Information Systems and Technology Architecture (VistA), VA medical centers, VA Health Eligibility Center, VA program offices, VISNs, VA Austin Automation Center, the Food and Drug Administration, DoD, HUD, Survey of Healthcare Experiences of Patients, EPRP, and the following Systems of Records: 'Patient Medical Records—VA' (24VA19), 'National Prosthetics Patient Database—VA' (33VA113), 'Healthcare Eligibility Records—VA' (89VA16), VA Veterans Benefits Administration automated record systems (including the Veterans and Beneficiaries Identification and Records Location Subsystem—VA (38VA23)), and subsequent iterations of those systems of records.

VA APPENDIX 4

Database name	Location
Addiction Severity Index	Veteran Affairs Medical Center, 7180 Highland Drive, Pittsburgh, PA 15206.
Bidirectional Health Information Exchange (BHIE)	SunGard, 1500 Spring Garden Street, Philadelphia, PA 19130.
VA Clinical Assessment Reporting and Tracking (CART) Program.	Denver VA Medical Center, 1055 Clermont Street, Denver, CO 80220.
Care Management Information System	Veterans Affairs Medical Center, University and Woodland Aves., Philadelphia, PA 19104.
Consolidated Mail Outpatient Pharmacy (CMOP) Centralized Database System.	Southwest CMOP, 3675 East Britannia Drive, Tucson, AZ 85706.
Continuous Improvement in Cardiac Surgery	Veteran Affairs Medical Center, 820 Clermont Street, Denver, CO 80220.
Converged Registries Solution	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Corporate Data Warehouse	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Cruetzfelet-Jakob Disease Lookback Dataset	Cincinnati VA Medical Center, 3200 Vine Street, Cincinnati, OH 45220.
Decision Support System	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Dental Encounter System	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Eastern Pacemaker Surveillance Center Database	Veteran Affairs Medical Center, 50 Irving Street NW. Washington, DC 20422.
The Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE).	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Emerging Pathogens Initiative	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Federal Health Information Exchange (FHIE)	SunGard, 1500 Spring Garden Street, Philadelphia, PA 19130.
Financial Clinical Data Mart	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Former Prisoner of War Statistical Tracking System	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.

VA APPENDIX 4—Continued

Database name	Location
Functional Status and Outcome Database	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Healthcare Associated Infections & Influenza Surveillance System (HAIISS) Data Warehouse.	Veteran Affairs Medical Center, 3801 Miranda Avenue, Palo Alto, CA 94304.
Home Based Primary Care	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Homeless Operational Management & Evaluation System (HOMES).	Austin Information Technology Center, 1615 Woodward Street, Austin, Texas 78772.
Homeless Veterans Registry	Austin Automation Center, 1615 Woodward Street, Austin, TX 78772.
Injury Data Store	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Mammography Quality Standards VA	Veteran Affairs Medical Center, 508 Fulton Street, Durham, NC 27705.
Master Patient Index	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Medical SAS File (MDP) (Medical District Planning (MEDIPRO)).	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Missing Patient Register	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
National Mental Health Database System	Veteran Affairs Medical Center, 7180 Highland Drive, Pittsburgh, PA 15206.
National Medical Information System	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
National Survey of Veterans	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Office of Quality and Performance (OQP)	OQP Data Center, 601 Keystone Park Dr., Suite 800, Morrisville, NC 27560.
Parkinson's Disease Research, Education, and Clinical Centers Registry.	Veterans Affairs Medical Center, 4150 Clement St., San Francisco,, CA 94121.
Patient Assessment File	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Pharmacy Benefits Management	Veterans Affairs Medical Center, 5th Avenue and Roosevelt Road, Hines, IL 60141.
Radiation Exposure Inquiries Database	Office of Information Field Office, 1335 East/West Hwy., Silver Spring, MD 20910.
Remote Order Entry System	Denver Distribution Center, 155 Van Gordon Street, Lakewood, CO 80228–1709.
Regional Data Warehouses (RDW)	Region 1 Data Warehouse, Herakles Data Center, 1100 North Market Blvd, Sacramento, CA 95834.
	Region 2 Data Warehouse, Little Rock VA Medical Center, IRM/Bldg 102, 2200 Ft. Roots Drive, North Little Rock, AR 72114.
	Region 3 Data Warehouse, Durham VAMC, 508 Fulton Street, Durham, NC 27705.
	Region 4 Data Warehouse, Sungard Availablity Services, 401 N. Broad Street, Suite 11.803, Philadelphia, PA 19108.
Resident Assessment Instrument/Minimum Data Set	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Short Form Health Survey for Veterans	Veterans Affairs Medical Center, 200 Springs Rd., Bedford, MA 01730.
VA National Clozapine Registry	Veteran Affairs Medical Center, 4500 South Lancaster Road, Dallas, TX 75216.
VA Polytrauma Rehabilitation Center/Traumatic Brain Injury (TBI) Model System Database.	Craig Hospital, 3425 S. Clarkson St., Englewood, CO 80113.
VA Vital Status File	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Veterans Administration Central Cancer Registry	Veteran Affairs Medical Center, 50 Irving Street NW., Washington, DC 20422.
Veterans Informatics, Information and Computing Infrastructure (VINCI).	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.
Veterans Integrated Service Network Support Service Center Databases.	Austin Information Technology Center, 1615 Woodward Street, Austin, TX 78772.

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FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, et. al

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, 476, and 489

[CMS–1588–P]

RIN 0938–AR12

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems and to implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and other legislation. These changes would be applicable to discharges occurring on or after October 1, 2012. We also are proposing to update the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The updated rate-of-increase limits would be effective for cost reporting periods beginning on or after October 1, 2012.

We are proposing to update the payment policy and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implementing certain statutory changes made by the Affordable Care Act. These proposed changes would be applicable to discharges occurring on or after October 1, 2012.

In addition, we are proposing changes relating to determining a hospital's full-time equivalent (FTE) resident cap for the purpose of graduate medical education (GME) and indirect medical education (IME) payments. We are proposing new requirements or revised requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that are participating in Medicare. We also are proposing new administrative, data completeness, and extraordinary circumstance waivers or extension requests requirements, as well as a reconsideration process, for quality reporting by ambulatory surgical centers (ASCs) that are participating in Medicare.

We are proposing requirements for the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program.

DATES: *Comment Period:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EDT on June 25, 2012.

ADDRESSES: When commenting, please refer to file code CMS–1588–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation at *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' and enter the file code CMS–1588–P to submit comments on this proposed rule.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1588–P, P.O. Box 8011, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1588–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

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For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Tzvi Hefter, (410) 786–4487, and Ing-Jye Cheng, (410) 786–4548, Operating Prospective Payment, MS–DRGs, Hospital Acquired Conditions (HAC), Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH), and Postacute Care Transfer Issues.

Michele Hudson, (410) 786–4487, and Judith Richter, (410) 786–2590, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Mollie Knight, (410) 786–7948, Market Basket for LTCHs Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

James Poyer, (410) 786–2261, Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786–0641, Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Elizabeth Goldstein, (410) 786–6665, Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

James Poyer, (410) 786–2261, and Barbara Choo, (410) 786–4449, Inpatient Psychiatric Facility Quality Reporting Issues and PPS-Exempt Cancer Hospital Quality Reporting Issues.

Anita Bhatia, (410) 786–7236, Ambulatory Surgical Center Quality Reporting Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions at the Web site to view public comments.

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Tables Available Only Through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to this proposed rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published as part of the annual IPPS and LTCH PPS proposed and final rules. Instead, these tables will be available only through the Internet. The IPPS tables for this proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.* Click on the link on the left side of the screen titled, ''FY 2013 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2013 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1588–F. For complete details on the availability of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Nisha Bhat at (410) 786–4487.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASC Ambulatory surgical center
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASCQR Ambulatory Surgical Center Quality Reporting
ASITN American Society of Interventional and Therapeutic Neuroradiology
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CDC Center for Disease Control and Prevention
CIPI Capital input price index
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated Metropolitan Statistical Area
COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA Cost-of-living adjustment
CoP [Hospital] condition of participation
CPI Consumer price index
CRNA Certified Registered Nurse Anesthetist
CY Calendar year
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
ECI Employment cost index
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
FAH Federation of Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FQHC Federally qualified health center
FTE Full-time equivalent
FY Fiscal year
GAAP Generally Accepted Accounting Principles
GAF Geographic Adjustment Factor
GME Graduate medical education
HACs Hospital-acquired conditions
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCRIS Hospital Cost Report Information System
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification

ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
IGI IHS Global Insight, Inc.
IHS Indian Health Service
IME Indirect medical education
I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
LTCHQR Long-Term Care Hospital Quality Reporting
MA Medicare Advantage
MAC Medicare Administrative Contractor
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MCV Major cardiovascular condition
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NHSN National Healthcare Safety Network
NQF National Quality Forum
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991 (Pub. L. 104–113)
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS'] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1996, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB Executive Office of Management and Budget
OPM U.S. Office of Personnel Management
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PCH PPS-exempt cancer hospital
PCHQR PPS-exempt cancer hospital quality reporting
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPACA Patient Protection and Affordable Care Act, Public Law 111–148
PPI Producer price index
PPS Prospective payment system
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PS&R Provider Statistical and Reimbursement (System)
QIG Quality Improvement Group, CMS
QIO Quality Improvement Organization
RCE Reasonable compensation equivalent
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SFY State fiscal year
SIC Standard Industrial Classification
SNF Skilled nursing facility
SOCs Standard occupational classifications
SOM State Operations Manual
SSO Short-stay outlier
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
TPS Total Performance Score
UHDDS Uniform hospital discharge data set

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for the Medicare hospitals under the long-term care hospital prospective payment system (LTCH PPS). It also makes policy changes to programs associated with Medicare IPPS hospitals and LTCHs.

Under various statutory authorities, we are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2013. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a

reasonable cost basis, the Secretary use a prospective payment system (PPS).

• Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.

• Sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554 (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.

• Sections 1814(l), 1820, and 1834(g) of the Act, which specifies that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.

• Section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix.

• Section 1886(d)(4)(D) of the Act, which addresses certain hospital-acquired conditions (HACs), including infections. Section 1886(d)(4)(D) of the Act specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions. Section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were present on admission (POA). Section 1886(d)(4)(D)(i) of the Act specifies that effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not POA.

• Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.

• Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase in payments to a subsection (d) hospital for a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.

• Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary. Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient VBP Program to hospitals for discharges occurring on or after October 1, 2012.

• Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which establishes the ''Hospital Readmission Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

2. Summary of the Major Provisions

a. MS–DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate prospective adjustment under section 1886(d)(3)(A)(vi) of the Act.

Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional one-time adjustment to the standardized amounts to offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90.

After accounting for adjustments made in FYs 2008 and 2009, we have found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90. Without making this adjustment, our actuaries estimated that annual aggregate payments would be increased by approximately $4 billion. Furthermore, an additional one-time adjustment of −5.8 percent would be required to fully recapture overpayments (estimated at approximately $6.9 billion) due to documentation and coding that occurred in FY 2008 and FY 2009, as required by section 7(b)(1)(B) of Public Law 110–90.

CMS has thus far implemented a −2.0 percent (of a required −3.9 percent) prospective adjustment, and completed the full one-time −5.8 percent recoupment adjustment (−2.9 percent in both FYs 2011 and 2012). In FY 2013, we are proposing to complete the remaining −1.9 percent prospective adjustment, while also making a +2.9 percent adjustment to remove the effect of the FY 2012 one-time recoupment adjustment. We have also determined that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. After accounting for adjustments made to the hospital-specific rate in FY 2011 and FY 2012, an additional prospective adjustment of −0.5 percent is necessary to complete the full −5.4 adjustment. We are proposing a full −0.5 percent adjustment to the hospital-specific rate, in keeping with our policy of applying equivalent adjustments, when applicable, to other subsection (d) hospital payment systems.

We also are proposing an additional adjustment to account for documentation and coding effects that occurred in FY 2010. After review of comments and recommendations from MedPAC, CMS analyzed FY 2010 claims

using the same methodology as previously applied to FYs 2008 and 2009 claims. CMS estimates that there was a 0.8 percentage point effect due to documentation and coding that did not reflect an actual increase in patient severity. Our actuaries estimate that this 0.8 percentage point increase resulted in additional aggregate payments of approximately $1.19 billion. Therefore, we are proposing an adjustment of −0.8 to the standardized amount and a −0.8 percent adjustment to the hospital-specific rate. This would result in a total documentation and coding adjustment of +0.2 percent (−1.9 plus +2.9 plus −0.8) to the standardized amount and a −1.3 percent (−0.5 plus −0.8) adjustment to the hospital-specific rate.

b. Hospital-Acquired Conditions (HACs)

Section 1886(d)(4)(D) specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions.

In this proposed rule, we are proposing two new conditions, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Pneumothorax with Venous Catheterization, for the HAC payment provisions for FY 2013 under section 1886(d)(4)(D) of the Act. We also are proposing to add diagnosis codes 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the existing Vascular Catheter-Associated Infection HAC category for FY 2013.

c. Reduction of Hospital Payments for Excess Readmissions

We are proposing a number of policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions of selected applicable conditions, which are acute myocardial infarction, heart failure, and pneumonia. We are proposing the applicable hospitals that included in the Hospital Readmissions Reduction Program, the methodology to calculate the adjustment factor, the portion of the hospital's payment that is reduced by the adjustment factor, and the process under which the hospitals have the opportunity to review and submit corrections for their readmissions information prior to the information being posted on the *Hospital Compare* Web site.

d. Long-Term Care Hospital-Specific Market Basket

We are proposing to update LTCH payment rates with a separate market basket comprised of data from only LTCHs, which we refer to as a ''LTCH-specific market basket.'' We are proposing to implement a stand-alone LTCH market basket based on FY 2009 Medicare cost report data. The method used to calculate the cost weights and the price proxies used are generally similar to those used in the FY 2008-based RPL market basket that was finalized for the FY 2012 IPPS/LTCH PPS final rule. The primary difference is that we are using data from LTCH providers only.

e. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Satellite Facilities and the Increase in the Number of Beds in LTCHs and LTCH Satellite Facilities

Moratoria on the implementation of certain LTCH payment policies and on the development of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities established under sections 114(c) and (d) of the MMSEA (Pub. L. 110–173) as amended by section 4302 of the ARRA (Pub. L. 111–5) and further amended by sections 3106 and 10312 of the Affordable Care Act are set to expire during CY 2012, under current law.

The moratoria established by these provisions delayed the full implementation of the following policies for 5 years beginning at various times in CY 2007:

- The full application of the ''25-percent payment adjustment threshold'' to certain LTCHs, including hospitals-within-hospitals (HwHs) and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2012, or cost reporting periods beginning on or after October 1, 2007, and before October 1, 2012, as applicable under the regulations at §§ 412.534 and 412.536.
- The inclusion of an ''IPPS comparable per diem amount'' option for payment determinations under the short stay outlier (SSO) adjustment at § 412.529 of the regulations for LTCH discharges occurring on or after December 29, 2007, but prior to December 29, 2012.
- The application of any one-time budget neutrality adjustment to the LTCH PPS standard Federal rate provided for in § 412.523(d)(3) of the regulations from December 29, 2007, through December 28, 2012.
- In general, the development of new LTCHs and LTCH satellite facilities, or increases in the number of beds in existing LTCHs and LTCH satellite facilities from December 29, 2007, through December 28, 2012, unless one of the specified exceptions to the particular moratorium was met.

In this proposed rule, we are proposing to extend the existing delay of the full implementation of the 25-percent payment adjustment threshold for an additional year; that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, as applicable. Although we are proposing to extend the moratoria relating to the application of the ''25-percent threshold'' payment adjustment for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, the moratoria will expire for several regulatory provisions for cost reporting periods beginning before July 1, 2012, prior to the effective date of the proposed extension, affecting freestanding LTCHs, grandfathered hospitals-within-hospitals (HwHs), and grandfathered satellites. This gap in the continued application of the moratorium is a result of the July 1, 2007 effective date of section 114(c)(1) of the MMSEA as amended by section 4302(a)(1) of the ARRA which was based on the former July 1 through June 30 regulatory cycle for the LTCH PPS.

We are proposing an additional 1-year extension in the delay of the full application of the 25-percent payment adjustment threshold policy because we believe, based on a recent research initiative, that we could soon be in a position to propose revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary. In light of this potential result, we believe it is prudent to avoid requiring LTCHs (or CMS systems) to implement the full reinstatement of the policy for what could be a relatively short period of time.

We are not proposing to make any changes to the SSO policy as it currently exists in the regulations at § 412.529.

Accordingly, consistent with the existing regulations at § 412.529(c)(3), for SSO discharges occurring on or after December 29, 2012, the ''IPPS comparable per diem amount'' option at § 412.529(c)(3)(i)(D) would apply to payment determinations for cases with a covered length of stay that was equal to or less than one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS (that is, the ''IPPS comparable threshold'').

The moratoria on the development of new LTCHs or LTCH satellite facilities and on an increase in the number of beds in existing LTCHs or LTCH satellite facilities are set to expire on December 29, 2012, under current law.

We are proposing to make a one-time prospective adjustment under § 412.523(d)(3) of the regulations (which would not apply to payments for discharges occurring on or before December 28, 2012, consistent with the statute) and to transition the application of this adjustment over a 3-year period. Regulations at § 412.523(d)(3) provide for the possibility of making a one-time prospective adjustment to the LTCH PPS rates so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.

f. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(vii) of the Act, hospitals are required to report data on measures selected by the Secretary for the Hospital IQR Program in order to receive the full annual percentage increase. In past rules, we have established measures for reporting and the process for submittal and validation of the data.

In this proposed rule, we are proposing programmatic changes to the Hospital IQR Program for the FY 2015 payment determination and subsequent years. These proposed changes would streamline and simplify the process for hospitals and reduce burden. We are proposing to reduce the number of measures in the Hospital IQR Program from 72 to 59 for the FY 2015 payment determination. We are proposing to remove 1 chart-abstracted measure and 16 claims based measures from the program for the FY 2015 payment determination and subsequent years. We are proposing to remove these measures for a number of reasons, including that these measures are losing NQF endorsement, are included in an existing composite measure, are duplicative of other measures in the Hospital IQR Program, or could otherwise be reported on *Hospital Compare* in the future under the authority of section 3008 of the Affordable Care Act. In addition, we are proposing to adopt three claims-based measures, one chart-abstracted measure and a survey-based measure regarding care transitions, which we will collect using the existing HCAHPS survey, to the measure set for the FY 2015 payment determination and subsequent years. We also are proposing to adopt a structural measure for the FY 2016 payment determination and subsequent years.

In an effort to streamline the rulemaking process, we are proposing to retain measures for all subsequent payment determinations, unless specifically stated otherwise, through rulemaking. We also are proposing to adopt certain changes to the Hospital IQR Program measures that arise out of the NQF endorsement maintenance process without going through further rulemaking to adopt such changes. To ensure that hospitals that participate in the Hospital IQR Program are submitting data for a full year, we are proposing that hospitals that would like to participate in the Hospital IQR Program for the first time must submit a completed Notice of Participation by December 31 of the calendar year preceding the first quarter of the calendar year in which chart-abstracted data submission is required for any given fiscal year. In addition, if a hospital wishes to withdraw from the program, it would have until May 15 prior to the start of the payment year affected to do so. In order reduce the burden associated with validation, we are proposing to reduce the base annual validation sample from 800 to 400, with an additional sample of up to 200 targeted hospitals. All hospitals failing validation would be included in the 200 hospital supplement, with a random sample drawn from hospitals meeting one or more additional targeting criteria. We also are proposing to require passing scores on both the chart-abstracted clinical process of care and hospital-acquired infection measure set groupings to pass validation, rather than only requiring one passing score for all validated measures.

g. Hospital Value-Based Purchasing Program

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital Inpatient VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B)(i) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent.

We previously published the requirements and related measures to implement the Hospital Inpatient VBP Program in a final rule issued in the **Federal Register** on April 29, 2011 (76 FR 26490, May 6, 2011, and 76 FR 26495 through 26511) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660). In this proposed rule, we are proposing to add requirements for the FY 2015 Hospital Inpatient VBP Program. Specifically, we are proposing to add one additional clinical process of care measure, AMI–10: Statin Prescribed at Discharge, and two additional outcomes measures—an AHRQ Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are proposing to add a measure of Medicare Spending per Beneficiary in the Efficiency domain.

3. Summary of Costs and Benefits

- Proposed FY 2013 Documentation and Coding Adjustment: Section 7(b)(1)(A) of Pub. L. 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate prospective adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional one-time adjustment to the standardized amounts to offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90.

After accounting for adjustments made in FYs 2008 and 2009, we have found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90.

Without making this adjustment, our actuaries estimated that annual aggregate payments would be increased by approximately $4 billion. Furthermore, an additional one-time adjustment of −5.8 percent would be required to fully recapture overpayments (estimated at approximately $6.9 billion) due to documentation and coding that occurred in FY 2008 and FY 2009, as required by section 7(b)(1)(B) of Public Law 110–90.

CMS has thus far implemented a −2.0 percent (of a required −3.9 percent) prospective adjustment, and completed the full one-time −5.8 percent recoupment adjustment (−2.9 percent in both FYs 2011 and 2012). In FY 2013, we are proposing to complete the remaining −1.9 percent prospective adjustment, while also making a +2.9 percent adjustment to remove the effect of the FY 2012 one-time recoupment adjustment. We have also determined that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. After accounting for adjustments made to the hospital-specific rate in FY 2011 and FY 2012, an additional prospective adjustment of −0.5 percent is necessary to complete the full −5.4 percent adjustment. We are proposing a full −0.5 percent adjustment to the hospital-specific rate, in keeping with our policy of applying equivalent adjustments, when applicable, to other subsection (d) hospital payment systems.

In addition, we are proposing an additional adjustment to account for documentation and coding effects that occurred in FY 2010. After review of comments and recommendations from MedPAC, CMS analyzed FY 2010 claims using the same methodology as previously applied to FYs 2008 and 2009 claims. CMS estimates that there was a 0.8 percentage point effect due to documentation and coding that did not reflect an actual increase in patient severity. Our actuaries estimate that this 0.8 percentage point increase resulted in additional aggregate payments of approximately $1.19 billion. Therefore we are proposing an adjustment of −0.8 to the standardized amount, and a −0.8 percent adjustment to the hospital-specific rate.

The total IPPS documentation and coding adjustment of +0.2 percent (−1.9 plus +2.9 plus −0.8) would increase total payments by approximately $200 million. The total adjustment to the hospital-specific rate would be −1.3 percent (−0.5 plus −0.8), and would decrease total payment by $312 million. The combined impact of the proposed FY 2013 documentation and coding adjustments would reduce total payments by approximately $112 million.

- Hospital-Acquired Conditions (HACs). For FY 2013, we are proposing to continue to implement section 1886 (d)(4)(D) of the Act that addresses certain hospital-acquired conditions (HACs), including infections. We are proposing to add two additional conditions for FY 2013, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Iatrogenic Pneumothorax with Venous Catheterization. The projected savings estimate for these two conditions is less than $1 million, with the total estimated savings from HACs for FY 2013 projected at $24 million dollars.
- Reduction to Hospital Payments for Excess Readmissions. We are proposing a number of policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions of selected applicable conditions, which are acute myocardial infarction, heart failure, and pneumonia. This provision is not budget neutral. A hospital's readmission payment adjustment is the higher of a ratio of a hospital's aggregate dollars for excess readmissions to their aggregate dollars for all discharges, or 0.99 (that is, or a 1-percent reduction) for FY 2013. In this proposed rule, we estimate that the Hospital Readmissions Reduction Program will result in a 0.3 percent decrease, or approximately $300 million, in payments to hospitals.
- Long-Term Care Hospital-Specific Market Basket. The proposed FY 2009-based LTCH-specific market basket update (as measured by percentage increase) for FY 2013 is currently forecasted to be the same as the market basket update based on the FY 2008-based RPL market basket at 3.0 percent (currently used under the LTCH PPS). Therefore, we are projecting that there would be no fiscal impact on the LTCH PPS payment rates in FY 2013 as a result of this proposal. In addition, we are proposing to update the labor-related share under the LTCH PPS for FY 2013 based on the proposed relative importance of each labor-related cost category in the proposed FY 2009-based LTCH-specific market basket. Although this proposal would result in a decrease in the LTCH PPS labor-related share for FY 2013, we are projecting that there would be no effect on aggregate LTCH PPS payments due to the regulatory requirement that any changes to the LTCH area wage adjustment (including the labor-related share) are adopted in a budget neutral manner.
- Update to the LTCH PPS Standard Federal Rate, including the Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Satellite Facilities and the Increase in the Number of Beds in LTCHs and LTCH Satellite Facilities. Based on the best available data for the 427 LTCHs in our database, we estimate that the changes we are presenting in the preamble and Addendum of this proposed rule, including the proposed update to the standard Federal rate for FY 2013, the proposed changes to the area wage adjustment for FY 2013, and changes to short-stay outliers and high cost outlier would result in an increase in estimated payments from FY 2012 of approximately $100 million (or about 1.9 percent). Although we are generally projecting an increase in payments for all LTCHs in FY 2013 as compared to FY 2012, we expect rural LTCHs to experience a larger than average increase in payments (3.6 percent) primarily due to the proposed changes to the area wage level adjustment. Rural hospitals generally have a wage index of less than 1; therefore, the proposed decrease to the labor-related share results in their proposed wage index reducing a smaller portion of the standard Federal rate, resulting in an estimated increase in payments in FY 2013 as compared to FY 2012. In addition, the effect of the proposed extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2012, is estimated to result in a payment impact of approximately $170 million to LTCHs. Overall, we estimate that the increase in aggregate LTCH PPS payments in FY 2013 will be $270 million.
- Hospital Inpatient Quality Reporting Program. In this proposed rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for FY 2015. We estimate that approximately 95 hospitals may not receive the full annual percentage increase in any fiscal year. However, at this time, information is not available to

determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for FY 2015.

We are proposing supplements to the chart validation process for the Hospital IQR Program. Starting with the FY 2015 payment determination, we are proposing a modest increase to the current Hospital IQR Program validation sample of 18 cases per quarter to 27 cases per quarter in order to capture data on CLABSI, CAUTI, and SSI measures. However, in order not to increase the Hospital IQR validation program's overall burden to hospitals, we are proposing to reduce the total sample size of hospitals included in the annual validation sample from 800 eligible hospitals to 600 eligible hospitals.

We provide payment to hospitals for the cost of sending charts to the CDAC contractor at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Our experience shows that the average chart received by the CDAC contractor is approximately 275 pages. The requirement of an additional 9 charts per hospital submitted for validation, combined with the decreased sample size, will result in approximately 1,800 additional charts per quarter being submitted to CMS by all selected hospitals. Thus, we estimate that we would expend approximately $66,600 per quarter to collect the additional charts we need to validate all measures.

- Hospital Value-Based Purchasing Program. The Hospital Value-Based Purchasing Program for FY 2013 is statutorily mandated to be budget neutral. We believe that the program's benefits will be seen in improved patient outcomes, safety, and experience of care. We cannot estimate these benefits in actual dollar and patient terms because the program does not commence until FY 2013 payments.

B. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations.

If the hospital is an approved teaching hospital, it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. Through and including FY 2006, a Medicare-dependent, small rural hospital (MDH) received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. As discussed below, for discharges occurring on or after October 1, 2007, but before October 1, 2012, an MDH will receive the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. (We note that the statutory provision for payments to MDHs expires at the end of FY 2012, that is, after September 30, 2012.) SCHs are the sole source of care in their areas, and MDHs are a major source of care for Medicare beneficiaries in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services ''in accordance with a prospective payment system established by the Secretary.'' The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under

the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR Part 412, Subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for rehabilitation hospitals and units (referred to as inpatient rehabilitation facilities (IRFs)), LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554 (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, Subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR parts 413 and 415.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) Applicable to FY 2013

The Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, made a number of changes that affect the IPPS and the LTCH PPS. (Pub. L. 111–148 and Pub. L. 111–152 are collectively referred to as the ''Affordable Care Act.'') A number of the provisions of the Affordable Care Act affect the updates to the IPPS and the LTCH PPS and providers and suppliers. The provisions of the Affordable Care Act that were applicable to the IPPS and the LTCH PPS for FYs 2010, 2011, and 2012 were implemented in the June 2, 2010 Federal Register notice (75 FR 31118), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50042) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51476).

In this proposed rule, we are proposing to implement, or continuing in FY 2013 to implement, the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS, the LTCH PPS, and PPS-exempt cancer hospitals:

- Section 3001 of Public Law 111–148, which provides for establishment of a hospital inpatient value-based purchasing program under which value-based incentive payments will be made in a fiscal year to hospitals that meet performance standards established for a performance period with respect to discharges occurring during FY 2014.
- Section 3004 of Public Law 111–148, which provides for the submission of quality data for LTCHs beginning in FY 2014 in order to receive the full annual update to the payment rates beginning with FY 2015 and the establishment of quality data measures by FY 2013 for the FY 2015 payment determination.
- Section 3005 of Public Law 111–148, which provides for the establishment of a quality reporting program for PPS-exempt cancer hospitals beginning with the FY 2014 program year, and for subsequent program years.
- Section 3025 of Public Law 111–148, which establishes a hospital readmissions reduction program and requires the Secretary to reduce payments to applicable hospitals with excess readmissions effective for discharges beginning on or after October 1, 2012.
- Section 3125 and 10314 of Public Law 111–148, which modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.
- Section 3401 of Public Law 111–148, which provides for the incorporation of productivity adjustments into the market basket updates for IPPS hospitals and LTCHs.
- Section 10324 of Public Law 111–148, which provides for a wage adjustment for hospitals located in frontier States.
- Sections 3401 and 10319 of Public Law 111–148 and section 1105 of Public Law 111–152, which revise certain market basket update percentages for

IPPS and LTCH PPS payment rates for FY 2013.

• Section 3137 of Public Law 111–148, which requires the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index under the IPPS. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by MedPAC in its June 2007 Report to Congress and to consult with relevant affected parties.

• Section 5503 of Public Law 111–148, as amended by Public Law 111–152 and section 203 of Public Law 111–309, which provides for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals, and the ''redistribution'' of the estimated number of FTE resident slots to other qualified hospitals. In addition, section 5503 requires the application of these provisions to IME in the same manner as the FTE resident caps for direct GME.

• Section 5506 of Public Law 111–148, which added a provision to the Act that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the aggregate number of FTE resident cap slots distributed is equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively.

D. Major Contents of This Proposed Rule

In this proposed rule, we are setting forth proposed changes to the Medicare IPPS for operating costs and for capital-related costs of acute care hospitals in FY 2013. We also are setting forth proposed changes relating to payments for IME costs and payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in this proposed rule, we are setting forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2013.

Below is a summary of the major changes that we are proposing to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include the following:

• Proposed changes to MS–DRG classifications based on our yearly review.

• Proposed application of the documentation and coding adjustment for FY 2013 resulting from implementation of the MS–DRG system.

• A discussion of the Research Triangle Institute, International (RTI) reports and recommendations relating to charge compression.

• Proposed recalibrations of the MS–DRG relative weights.

• Proposed changes to hospital-acquired conditions (HACs) and a listing and discussion of HACs, including infections, that would be subject to the statutorily required adjustment in MS–DRG payments for FY 2013.

• A discussion of the FY 2013 status of new technologies approved for add-on payments for FY 2012 and a presentation of our evaluation and analysis of the FY 2013 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Public Law 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include the following:

• The proposed FY 2013 wage index update using wage data from cost reporting periods beginning in FY 2009.

• Analysis and implementation of the proposed FY 2013 occupational mix adjustment to the wage index for acute care hospitals.

• Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications.

• The proposed adjustment to the wage index for acute care hospitals for FY 2013 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.

• The timetable for reviewing and verifying the wage data used to compute the proposed FY 2013 hospital wage index.

• Determination of the labor-related share for the proposed FY 2013 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

In section IV. of the preamble of this proposed rule, we discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412, 413, and 476, including the following:

• The proposed rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates.

• Proposed clarification regarding the duration of the classification status of SCHs.

• The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.

• Proposed payment adjustment for low-volume hospitals for FY 2013.

• The statutorily required IME adjustment factor for FY 2013, a clarification of the requirements of timely filing of claims for Medicare Advantage enrollees for IME, direct GME, and nursing and allied health education payment purposes, and a proposal to apply the timely filing requirements to the submission of no-pay bills for purposes of calculating the DSH payment adjustment.

• Proposal for counting labor and delivery beds in the formula for determining the payment adjustment for disproportionate share hospitals and IME payments.

• Discussion of the expiration of the MDH program in FY 2012.

• Proposed changes to the inpatient hospital update for FY 2013, including incorporation of a productivity adjustment.

• Proposed changes relating to GME and IME payments, including proposed changes in new growth period for new residency programs from 3 years to 5 years for new teaching hospitals; clarification related to the 5-year period following implementation of reductions and increases to hospitals' FTE resident caps; and proposals and clarifications related to the preservation of resident cap positions from closed hospitals.

• Proposed conforming changes to regulations relating to reporting requirements for pension costs for Medicare cost-finding purposes.

• Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.

• Proposed delay in the effective date of regulations relating to hospital routine services furnished under arrangements.

4. Proposed FY 2013 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2013 and

the proposed MS–DRG documentation and coding adjustment for FY 2013.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of this proposed rule, we discuss proposed changes to payments to certain excluded hospitals.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of this proposed rule, we set forth proposed changes to the payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2013. Specifically, we are proposing the following major changes: a 1-year extension of the moratorium on the full implementation of the ''25-percent threshold'' payment adjustment at 42 CFR 412.534 and 412.536; a ''one-time prospective adjustment'' to the standard Federal rate phased in over a 3-year period (which would not be applicable to payments for discharges occurring on or before December 28, 2012, consistent with the statute); an LTCH-specific market basket; and annual updates to the LTCH PPS standard Federal rate and to other payment factors.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of this proposed rule, we address—

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full applicable percentage increase.
- The proposed establishment of a quality reporting program for PPS-exempt cancer hospitals.
- Proposed requirements for the Hospital Value-Based Purchasing Program.
- Proposed revisions to the quality reporting measures under the LTCH quality reporting program.
- Proposed quality data reporting requirements for ambulatory surgical centers (ASCs).
- The establishment of the Inpatient Psychiatric Facilities Quality Reporting Program

8. Determining Proposed Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2013 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We also are proposing to establish the threshold amounts for outlier cases. In addition, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2013 for certain hospitals excluded from the IPPS.

9. Determining Proposed Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2013 prospective standard Federal rate. We also are proposing to establish the proposed adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

10. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, LTCHs, ASCs, and IPFs.

11. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2013 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The standard Federal rate for hospital inpatient services furnished by LTCHs.

12. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 1 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2012 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs under the IPPS, for hospitals and distinct part hospital units excluded from the IPPS. We addressed these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2012 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov*.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as DRGs) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS–DRG Reclassifications

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50053 through 50055), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. Proposed FY 2013 MS–DRG Documentation and Coding Adjustment, Including the Applicability to the Hospital-Specific Rates and the Puerto Rico-Specific Standardized Amount

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 751 MS–DRGs, which include 4 additional MS–DRGs that we adopted for FY 2012.) By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percent to the national standardized amount. We provided for phasing in this −4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90. Section 7(a) of Public Law110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective on October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent, and we finalized that adjustment through rulemaking (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment for FY 2009 was in addition to the −0.6 percent adjustment for FY 2008, yielding a combined effect of −1.5 percent.

2. Prospective Adjustment to the Average Standardized Amounts Required by Section 7(b)(1)(A) of Public Law 110–90

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

3. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Public Law 110–90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Public Law 110–90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 precisely matched the changes that occurred in those years. Public Law 110–90 requires that the Secretary only make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

4. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110–90, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 proposed and final rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065) and our own review of the methodologies recommended by various commenters that the methodology we employed to determine the required documentation and coding adjustments were sound.

5. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43767 through 43777), we

opted to delay the implementation of any documentation and coding adjustment until a full analysis case-mix changes based on FY 2009 claim data could be completed. We refer readers to the FY 2010 IPPS/LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 1.054 percent. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section 7(b)(1)(B) of Public Law 110–90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an ''appropriate'' adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believe we have some discretion as to the manner in which we apply the prospective adjustment of −3.9 percent. We indicated that applying the full prospective adjustment of −3.9 percent for FY 2011, in combination with the proposed recoupment adjustment of −2.9 percent in FY 2011 (discussed below) would require an aggregate adjustment of −6.8 percent. As we discuss extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. Therefore, we stated that we believed it was appropriate to not implement any or all of the −3.9 percent prospective adjustment in FY 2011 because we finalized a −2.9 percent recoupment adjustment for that year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870). We note that, as a result, payments in FY 2011 (and in each future year until we implement the requisite adjustment) would be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90. Our actuaries estimate that this 3.9 percentage point increase will result in an aggregate payment of approximately $4 billion. We also noted that payments in FY 2010 were also expected to be 3.9 percent higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90, which our actuaries estimated increased aggregate payments by approximately $4 billion in FY 2010.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a −2.0 percent prospective adjustment (a reduction of a proposed −3.15 percent adjustment) to the standardized amount to partially eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Due to the offsetting nature of the remaining recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90 (described in section II.D.6. of this preamble), and after considering other payment adjustments to FY 2012 rates proposed elsewhere in the FY 2012 proposed rule, we indicated that we believe a −2.0 percent adjustment would allow for a significant reduction in potential unrecoverable overpayments, yet would maintain a comparable adjustment level between FY 2011 and FY 2012, reflecting the applicable percentage increase with a documentation and coding adjustment. We stated that we recognize that an additional adjustment of −1.9 percent (3.9 percent minus 2.0 percent) would be required in future rulemaking to complete the necessary −3.9 adjustment to meet CMS' statutory requirement under section 7(b)(1)(A) of Public Law 110–90.

For FY 2013, we are proposing to complete the prospective portion of the adjustment required under section 7(b)(1)(B) of Public Law 110–90. We are proposing a −1.9 percent adjustment to the standardized amount for FY 2013. This adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We believe it is imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future years until a full adjustment is made. We believe that the offsetting nature of the FY 2012 recoupment adjustment (described in section II.D.6. of this preamble) will mitigate any negative financial impacts of this prospective adjustment.

6. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Public Law 110–90

As discussed in section II.D.3. of this preamble, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in rate adjustments over more than one year in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of −2.9 percent, representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. An adjustment of this magnitude allowed us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110–90 (that is, no later than FY 2012).

As we stated in prior rulemaking, a major advantage of making the −2.9 percent adjustment to the standardized

amount in FY 2011 was that, because the required recoupment adjustment is not cumulative, we anticipated removing the FY 2011 −2.9 percent adjustment from the rates (in other words, making a positive 2.9 percent adjustment to the rates) in FY 2012, at the same time that the law required us to apply the remaining approximately −2.9 percent adjustment required by section 7(b)(1)(B) of Public Law 110–90.

Therefore, for FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012.

The −2.9 percent adjustment in each of the 2 previous fiscal years completed the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009. In this FY 2013 proposed rule, we are proposing to make a final +2.9 percent adjustment to the standardized amount. This adjustment would remove the effect of the onetime −2.9 percent adjustment implemented in FY 2012. We continue to believe that this is a reasonable and fair approach that satisfies the requirements of the statute while substantially moderating the financial impact on hospitals.

7. Background on the Application of the Documentation and Coding Adjustment to the Hospital-Specific Rates

Under section 1886(d)(5)(D)(i) of the Act, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge. Under section 1886(d)(5)(G) of the Act, MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate based on the greatest of the FY 1982, FY 1987, or FY 2002 costs per discharge. (We note that the MDH program expires in FY 2012, as discussed in section IV.H. of this proposed rule.) In the FY 2008 IPPS final rule with comment period (72 FR 47152 through 47188), we established a policy of applying the documentation and coding adjustment to the hospital-specific rates. In that final rule with comment period, we indicated that because SCHs and MDHs use the same DRG system as all other hospitals, we believe they should be equally subject to the budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. In establishing this policy, we relied on section 1886(d)(3)(A)(vi) of the Act, which provides us with the authority to adjust ''the standardized amount'' to eliminate the effect of changes in documentation and coding that do not reflect real change in case-mix.

However, in the final rule that appeared in the **Federal Register** on November 27, 2007 (72 FR 66886), we rescinded the application of the documentation and coding adjustment to the hospital-specific rates retroactive to October 1, 2007. In that final rule, we indicated that, while we still believe it would be appropriate to apply the documentation and coding adjustment to the hospital-specific rates, upon further review, we decided that the application of the documentation and coding adjustment to the hospital-specific rates is not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting ''the standardized amount'' under section 1886(d) of the Act and does not mention adjusting the hospital-specific rates.

In the FY 2009 IPPS proposed rule (73 FR 23540), we indicated that we continued to have concerns about this issue. Because hospitals paid based on the hospital-specific rate use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. In section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rates should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. The special exceptions and adjustment provision authorizes us to provide ''for such other exceptions and adjustments to [IPPS] payment amounts * * * as the Secretary deems appropriate.'' In the FY 2009 IPPS final rule (73 FR 48448 through 48449), we indicated that, for the FY 2010 rulemaking, we planned to examine our FY 2008 claims data for hospitals paid based on the hospital-specific rate. We further indicated that if we found evidence of significant increases in case-mix for patients treated in these hospitals that do not reflect real changes in case-mix, we would consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates under our authority in section 1886(d)(5)(I)(i) of the Act.

In response to public comments received on the FY 2009 IPPS proposed rule, we stated in the FY 2009 IPPS final rule that we would consider whether such a proposal was warranted for FY 2010. To gather information to evaluate these considerations, we indicated that we planned to perform analyses on FY 2008 claims data to examine whether there has been a significant increase in case-mix for hospitals paid based on the hospital-specific rate. If we found that application of the documentation and coding adjustment to the hospital-specific rates for FY 2010 was warranted, we indicated that we would propose to make such an adjustment in the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule.

8. Documentation and Coding Adjustment to the Hospital-Specific Rates for FY 2011 and Subsequent Fiscal Years

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule and final rule (74 FR 24098 through 24100 and 74 FR 43775 through 43776, respectively), we discussed our retrospective evaluation of the FY 2008 claims data for SCHs and MDHs using the same methodology described earlier for other IPPS hospitals. We found that, independently for both SCHs and MDHs, the change due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 slightly exceeded the proposed 2.5 percent result discussed earlier for other

IPPS hospitals, but did not significantly differ from that result. We refer readers to those FY 2010 proposed and final rules for a more complete discussion.

As we have noted previously, because hospitals paid on the basis of their hospital-specific rate, including SCHs (and MDHs until the end of FY 2012), use the same MS–DRG system as all other IPPS hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patient severity of illness. Therefore, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. We believe the documentation and coding estimates for all subsection (d) hospitals should be the same. While the findings for the documentation and coding effect for all IPPS hospitals are similar to the effect for SCHs (and were slightly different to the effect for MDHs), we continue to believe that this is the appropriate policy so as to neither advantage or disadvantage different types of providers. Our best estimate, based on the most recently available data, is that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments to hospitals paid on the basis of their hospital-specific rate. We note that, for FY 2013, this adjustment would only apply the SCHs because the MDH program expires in FY 2012 (as discussed in section IV.G. of this preamble). Unlike the case of standardized amounts paid to IPPS hospitals, prior to FY 2011, we had not made any previous adjustments to the hospital-specific rates paid to SCHs (and MDHs) to account for documentation and coding changes. Therefore, the entire −5.4 percent adjustment needed to be made, as opposed to a −3.9 percent remaining adjustment for IPPS hospitals.

After finalizing a −2.9 percent prospective adjustment in FY 2011 (75 FR 50067 through 50071), we finalized a prospective adjustment to the hospital-specific rate of −2.0 percent for FY 2012 (76 FR 51499) instead of our proposed adjustment of −2.5 percent. Making this level of adjustment allows CMS to maintain, for FY 2012, consistency in payment rates for different IPPS hospitals paid using the MS–DRG. We indicated in the final rule that because this −2.0 percent adjustment no longer reflects the entire remaining requirement adjustment amount of −2.5 percent, an additional −0.5 percent adjustment to the hospital-specific payment rates would be required in future rulemaking.

For this FY 2013 proposed rule, we are proposing to complete the remaining prospective adjustment to account for the documentation and coding effect that occurred in FY 2008 and FY 2009 by applying a −0.5 percent adjustment to the hospital-specific rate. We continue to believe that SCHs had the same opportunity to benefit from improvements in documentation and coding that did not reflect an increase in patient severity, and we continue to believe that any resulting adjustments should be applied similarly to all subsection (d) hospitals, when possible. In FY 2013, we are proposing a prospective adjustment of −1.9 percent to the standardized amount. Therefore, we believe it is also appropriate to propose a −0.5 percent adjustment to the hospital-specific rate for FY 2013.

9. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

a. Background

Puerto Rico hospitals are paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As noted previously, the documentation and coding adjustment we adopted in the FY 2008 IPPS final rule with comment period relied upon our authority under section 1886(d)(3)(A)(vi) of the Act, which provides the Secretary the authority to adjust ''the standardized amounts computed under this paragraph'' to eliminate the effect of changes in documentation and coding that do not reflect real changes in case-mix. Section 1886(d)(3)(A)(vi) of the Act applies to the national standardized amounts computed under section 1886(d)(3) of the Act, but does not apply to the Puerto Rico-specific standardized amount computed under section 1886(d)(9)(C) of the Act.

While section 1886(d)(3)(A)(vi) of the Act is not applicable to the Puerto Rico-specific standardized amount, we believe that we have the authority to apply the documentation and coding adjustment to the Puerto Rico-specific standardized amount using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. Similar to SCHs that are paid based on the hospital-specific rate, we believe that Puerto Rico hospitals that are paid based on the Puerto Rico-specific standardized amount should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patient severity of illness. Consistent with the approach described for SCHs and MDHs in the FY 2009 IPPS final rule (73 FR 48449), we indicated that we planned to examine our FY 2008 claims data for hospitals in Puerto Rico. We indicated in the FY 2009 IPPS proposed rule (73 FR 23541) that if we found evidence of significant increases in case-mix for patients treated in these hospitals, we would consider proposing to apply documentation and coding adjustments to the FY 2010 Puerto Rico-specific standardized amount under our authority in section 1886(d)(5)(I)(i) of the Act.

b. Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate was that, for documentation and coding that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments from the Puerto Rico-specific rate. As we stated above, we believe it important to maintain both consistency and equity among all hospitals paid on the basis of the same MS–DRG system. At the same time, however, we recognize that the estimated cumulative impact on aggregate payment rates resulting from implementation of the MS–DRG system was smaller for Puerto Rico hospitals as compared to IPPS hospitals and SCHs. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50072 through 50073), we stated that we believed that a full prospective adjustment was the most appropriate means to take into full account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between hospitals paid on the basis of different prospective rates.

Because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, we proposed no further adjustment in the proposed rule for FY 2012. For FY 2013, we also are not proposing any adjustment to the Puerto Rico-specific rate.

10. Proposed Prospective Adjustments for FY 2010 Documentation and Coding Effect

Section 7(b)(1)(A) of Public Law 110–90 required CMS to make prospective documentation and coding adjustments under section 1886(d)(3)(A)(iv) of the Act if, based upon a review of FY 2008 and FY 2009 discharges, we determined that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix during FY 2008 or FY 2009 and that were different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90. However, section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case-mix. After review of comments and recommendations received in a FY 2012 comment letter from MedPAC (available on the Internet at: *http://www.medpac.gov/documents/06172011_FY12IPPS_MedPAC_COMMENT.pdf*), we analyzed claims data in FY 2010 to determine whether any additional adjustment would be required to ensure that the introduction of MS–DRGs was implemented in a budget neutral manner. While we expect that the impacts of documentation and coding behavior in response to the introduction of MS–DRGs in FY 2008 will eventually decline to insignificant levels, we analyzed FY 2010 data on claims paid through December 2011 using the same claims-based methodology as described in previous rulemaking (73 FR 43768 and 43775). We determined a total prospective documentation and coding effect of 1.008 percent for FY 2010. Our actuaries have estimated that this 0.8 percentage point increase resulted in an increase in aggregate payments of approximately $1.19 billion in FY 2010. Therefore, we also are proposing an additional −0.8 percent adjustment to account for the effects of documentation and coding changes that did not reflect real changes in case-mix in FY 2010.

The combined total prospective adjustment to the standardized amount proposed for FY 2013 under Public Law 110–90 to account for documentation and coding effects in FY 2008 and FY 2009 and under section 1886(d)(3)(A)(vi) of the Act to account for documentation and coding effect in FY 2010 is −2.7 percent (−1.9 percent plus −0.8 percent). The proposed adjustment would eliminate the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008, 2009, 2010. While we are making no proposals regarding future fiscal years at this time, we plan to continue to monitor and analyze additional claims data and make adjustments, when necessary, as authorized under 1886(d)(3)(A)(vi) of the Act. We note that the proposed total adjustment to the proposed FY 2013 standardized amount would be +0.2 percent because these prospective adjustments will be offset by the completion of the recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90, as discussed below.

We note that while we have decided to review FY 2010 claims data to determine whether additional prospective adjustments are necessary (as discussed earlier), section 7(b)(1)(B) of Public Law 110–90 does not authorize CMS to calculate any retrospective adjustment for overpayments made in FY 2010, nor to recover any related overpayments beyond FY 2012. The Secretary's authority under section 1886(d)(3)(A)(vi) of the Act is limited to prospective adjustments.

	Remaining prospective adjustment for FYs 2008–2009	Prospective adjustment for FY 2010	Proposed prospective adjustment for FY 2013	Removal of onetime recoupment adjustment in FY 2013	Combined proposed documentation & coding adjustment for FY 2013
Level of Adjustments	−1.9%	−0.8%	−2.7%	+2.9%	+0.2%

Consistent with our proposal for IPPS hospitals paid on the basis of the standardized amount, our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act, and based upon our review of FY 2010 claims data, we also are proposing an additional −0.8 percent adjustment to the hospital-specific rate to account for documentation and coding changes in FY 2010 that did not reflect real changes in case-mix. We believe that a full prospective adjustment for hospitals paid based on the hospital-specific rate is the most appropriate means to take into account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between hospitals paid on the basis of different prospective rates. Therefore, we are proposing a combined adjustment of −1.3 percent (−0.5 percent + −0.8 percent) to the hospital-specific rate, accounting for all documentation and coding effects observed between FY 2008 though FY 2010.

Based upon our analysis of FY 2010 claims data, we found no significant additional effect of documentation and coding in FY 2010 that would warrant any additional adjustment to the Puerto Rico-specific rate.

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effects. Interested individuals may still order these files through the Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: a Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

Mailing address if using the U.S. Postal Service: Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail: Centers for Medicare & Medicaid Services, OFM/Division of Accounting—RDDC, 7500 Security Boulevard, C3–07–11, Baltimore. MD 21244–1850.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR

47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

As we implemented cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to ''charge compression,'' which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single CCR is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to the Research Triangle Institute, International (RTI) to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the cost-to-charge ratios (CCRs) across services within cost centers. For a detailed summary of RTI's findings, recommendations, and public comments that we received on the report, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48452 through 48453).

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for ''Medical Supplies Charged to Patients'' and another line for ''Implantable Devices Charged to Patients.'' We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS/LTCH PPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS–DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals should use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. Accordingly, a new subscripted line 55.30 for ''Implantable Devices Charged to Patients'' was created in July 2009 as part of CMS' Transmittal 20 update to the cost report Form CMS–2552–96. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458, respectively) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI also found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (MRI), and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and the OPPS relative weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRI, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the costs from charges on claims data. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRI, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS 2552–10. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of the reasons for the creation of standard cost centers for CT scans, MRI, and cardiac catheterization.) The new standard cost centers for CT scans, MRI, and cardiac catheterization are effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

2. Summary of Policy Discussion in FY 2012

In the FY 2009 IPPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new ''Implantable Devices Charged to Patients'' cost center to develop a CCR for Implantable Devices Charged to Patients in the FY 2012 or FY 2013 IPPS rulemaking cycle. However, as noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report CMS 2552–10, we determined that a new CCR for Implantable Devices Charged to Patients might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRI, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077).

Accordingly, during the FY 2012 IPPS rulemaking (76 FR 51502), we assessed the availability of data in the ''Implantable Devices Charged to Patients'' cost center. In order to develop a robust analysis regarding the use of cost data from the ''Implantable Devices Charged to Patients'' cost center, it was necessary to have a critical mass of cost reports filed with data in this cost center. We checked the availability of data in the ''Implantable Devices Charged to Patients'' cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for ''Implantable Devises Charged to Patients'' for use in calculating the MS–DRG relative weights for FY 2012. We indicated that we would reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

3. Discussion for FY 2013

To calculate the MS–DRG relative weights, we use two data sources: the MedPAR file as the claims data source and the HCRIS as the cost data source. We adjust the charges from the claims to costs by applying the 15 national average CCRs developed from the cost reports. In the past several years, we have made progress in changing the cost report to add the ''Implantable Devices Charged to Patients'' cost center. At this time, there is a sizeable number of hospitals in the FY 2010 HCRIS that have reported data for ''Implantable Devices Charged to Patients'' on their cost reports beginning during FY 2010. However, we note that, during the development of this proposed rule, we have been able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010. This is because cost reports with fiscal year begin dates of May 1, 2010,

through September 30, 2010, were filed on the new cost report Form 2552–10, and cost reports filed on the Form 2552–10 are not currently accessible in the HCRIS. Normally, we pull the HCRIS dataset that is 3 years prior to the IPPS fiscal year (that is, for the FY 2013 relative weights, we would use the FY 2010 HCRIS, which includes data from cost reports that begin on or after October 1, 2009, and before October 1, 2010). However, because data from the Form 2552–10 cost reports are not currently available, to ensure that the relative weights are calculated with a data set that is as comprehensive and accurate as possible, we are proposing to calculate the FY 2013 relative weights with data from FY 2010 cost reports for providers with fiscal year begin dates of on or after October 1, 2009, and before May 1, 2010, and to back fill with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. Further complicating matters is that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims is not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believe that we have no choice but to propose to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. When we do have the necessary supplies and implantable device data on the claims in the MedPAR file to create distinct CCRs for supplies and implantable devices, perhaps for FY 2014, we also hope that we will have data for an analysis of creating distinct CCRs for MRI, CT scans, and cardiac catheterization. Prior to proposing to create these CCRs, we will first thoroughly analyze and determine the impacts of the data. Distinct CCRs for implantable devices, MRIs, and CT scans would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

F. Preventable Hospital-Acquired Conditions (HACs), Including Infections

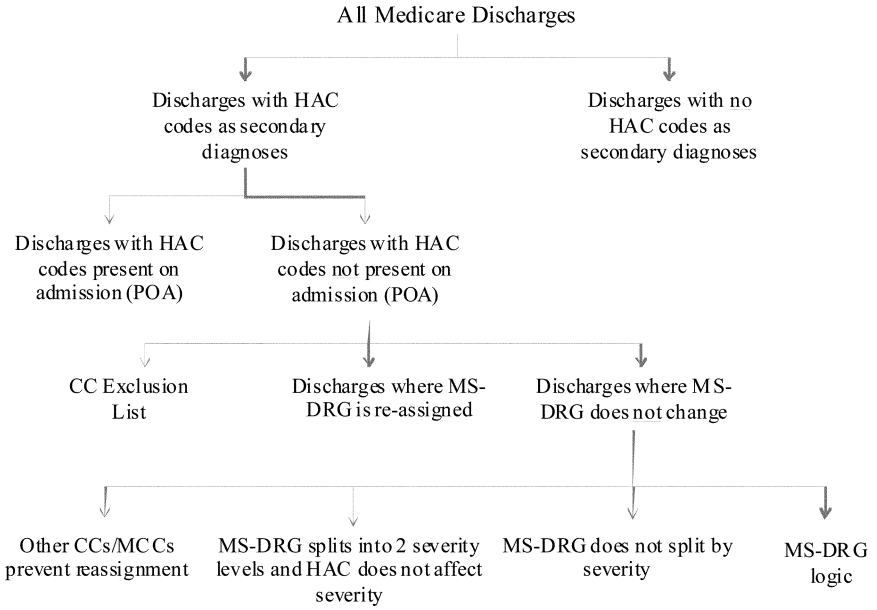
1. Background

Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. This provision is part of an array of Medicare tools that we are using to promote increased quality and efficiency of care. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

However, the treatment of certain conditions can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may generate an outlier payment. Because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS–DRG system that took effect in FY 2008 and that has been refined through rulemaking in subsequent years, certain conditions can generate higher payments even if the outlier payment requirements are not met. Under the MS–DRG system, there are currently 261 sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or an MCC. The presence of a CC or an MCC generally results in a higher payment.

Section 1886(d)(4)(D) specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) Are high cost, high volume, or both; (b) are assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions.

Effective for discharges occurring on or after October 1, 2008, pursuant to the authority of section 1886(d)(4)(D) of the Act, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not present on admission (POA). Thus, if a selected condition that was not POA manifests during the hospital stay, it is considered a HAC and the case is paid as though the secondary diagnosis was not present. However, even if a HAC manifests during the hospital stay, if any nonselected CC/MCC appears on the claim, the claim will be paid at the higher MS–DRG rate. In addition, Medicare continues to assign a discharge to a higher paying MS–DRG if a selected condition is POA. When a HAC is not POA, payment can be effected in a manner shown in the diagram below.



2. HAC Selection

Beginning in FY 2007, we have set forth proposals, and solicited and responded to public comments, to implement section 1886(d)(4)(D) of the Act through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, including a detailed discussion of the collaborative interdepartmental process and public input regarding selected and potential candidate HACs, we refer readers to the following rules: The FY 2007 IPPS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPPS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPPS proposed rule (73 FR 23547) and final rule (73 FR 48471); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080); and the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25810 through 25816) and final rule (76 FR 51504 through 51522). A complete list of the 10 current categories of HACs is included on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html*.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25813 through 25814) and FY 2012 IPPS/LTCH PPS final rule (76 FR 51507 through 50509), we proposed but did not finalize the candidate condition Contrast-Induced Acute Kidney Injury. Instead, we deferred the decision making on this condition as a selected HAC until future rulemaking and such a time when improved coding for the condition is available.

3. Present on Admission (POA) Indicator Reporting

Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. In previous rulemaking, we provided both CMS and CDC Web site resources that are available to hospitals for assistance in this reporting effort. For detailed information regarding these sites and materials, including the application and use of POA indicators, we refer the reader to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 through 51507).

As discussed in previous IPPS proposed and final rules, there are five POA indicator reporting options, as defined by the *ICD–9–CM Official Guidelines for Coding and Reporting:* Under the HAC policy, we treat HACs coded with ''Y'' and ''W'' indicators as POA and allow the condition on its own to cause an increased payment at the CC/MCC level. We treat HACs coded with ''N'' and ''U'' indicators as Not Present on Admission (NPOA) and do not allow the condition on its own to cause an increased payment at the CC/MCC level. We refer readers to the following rules for a detailed discussion: The FY 2009 IPPS proposed rule (73 FR 23559) and final rule (73 FR 48486 through 48487); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43784 through 43785); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23881 through 23882) and final rule (75 FR 50081 through 50082); and the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25812 through 25813) and final rule (76 FR 51506 through 51507).

Indicator	Descriptor
Y	Indicates that the condition was present on admission.
W	Affirms that the hospital has determined that, based on data and clinical judgment, it is not possible to document when the onset of the condition occurred.
N	Indicates that the condition was not present on admission.
U	Indicates that the documentation is insufficient to determine if the condition was present at the time of admission.
1	Signifies exemption from POA reporting. CMS established this code as a workaround to blank reporting on the electronic 4010A1. A list of exempt ICD–9–CM diagnosis codes is available in the *ICD–9–CM Official Guidelines for Coding and Reporting.*

Beginning on or after January 1, 2011, hospitals were required to begin reporting POA indicators using the 5010 electronic transmittal standards format. The 5010 format removes the need to report a POA indicator of ''1'' for codes that are exempt from POA reporting. We have issued CMS instructions on this reporting change as a One-Time Notification, Pub. No. 100–20, Transmittal No. 756, Change Request 7024, effective on August 13, 2010, which can be located at the following link on the CMS Web site: *http://www.cms.gov/manuals/downloads/Pub100_20.pdf*. However, for claims that continue to be submitted using the 4010 electronic transmittal standards format, the POA indicator of ''1'' is still necessary because of reporting restrictions from the use of the 4010 electronic transmittal standards format.

In addition, as discussed elsewhere in section III.G.9. of the preamble of this proposed rule, the 5010 format allows the reporting and effective January 1, 2011, the processing of up to 25 diagnoses and 25 procedure codes. As such, it is necessary to report a valid POA indicator for each diagnosis code, including the principal and all secondary diagnoses up to 25.

4. HACs and POA Reporting in ICD–10–CM and ICD–10–PCS

As we stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 and 51507), in preparation for the transition to the ICD–10–CM and ICD–10–PCS code sets, further information regarding the use of the POA indicator with the ICD–10–CM/ICD–10–PCS classifications as they pertain to the HAC policy will be discussed in future rulemaking.

At the March 5, 2012 meeting of the ICD–9–CM Coordination and Maintenance Committee, an announcement was made with regard to the availability of the ICD–9–CM HAC list translation to ICD–10–CM and ICD–10–PCS code sets. Participants were informed that the list of the current ICD–9–CM selected HACs has been translated into codes using the ICD–10–CM and ICD–10–PCS classification system. It was recommended that the public review this list of ICD–10–CM/ICD–10–PCS code translations of the current selected HACs available on the CMS Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. The translations can be found under the link titled ICD–10–CM/PCS MS–DRG v29 Definitions Manual Table of Contents—Full Titles—HTML Version in Appendix I—Hospital Acquired Conditions (HACs). The translation list also is available on the CMS Web page at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html*. We encourage the public to submit comments on these translations through the HACs Web page using the CMS ICD–10–CM/PCS HAC Translation Feedback Mailbox that has been set up for this purpose under the Related Links section titled ''CMS HAC Feedback.'' The final HAC list translation from ICD–9–CM to ICD–10–CM/ICD–10–PCS will be subject to formal rulemaking.

In the meantime, we continue to encourage readers to review the educational materials and draft code sets currently available for ICD–10–CM/ICD–10–PCS on the CMS Web site at: *http://www.cms.gov/ICD10/*. In addition, the draft ICD–10–CM/ICD–10–PCS coding guidelines can be viewed on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.htm*.

5. Proposed Changes to the HAC Policy for FY 2013

a. Proposed Additional Diagnosis Codes to Existing HACs

As changes to diagnosis codes and new diagnosis codes have been proposed and finalized for the list of CCs and MCCs, we have modified the list of selected HACs to reflect these changes. While there are not any new diagnosis codes being proposed for FY 2013, there were new and revised diagnosis codes effective October 1, 2011 (FY 2012) that were not finalized in time for inclusion in the FY 2012 IPPS rulemaking. Therefore, we are now proposing to add two of these codes to an existing HAC category. We are proposing to add diagnosis codes 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the Vascular Catheter-Associated Infection HAC category for FY 2013. These codes were created in response to a request discussed at the March 9–10, 2011 ICD–9–CM Coordination and Maintenance Committee meeting to better identify specific types of infections (systemic vs. local) that occur as a result of central venous catheter placement.

Previously, there was only one existing HAC code (999.31 (Infection due to central venous catheter)) in the Vascular Catheter-Associated Infection HAC category. With the creation of codes 999.32 and 999.33, effective October 1, 2011, the title for code 999.31 was revised to ''Other and unspecified infection due to central venous catheter.'' Therefore, codes 999.32 and 999.33 provide further specificity as to the type of infection due to a central venous catheter. We refer readers to page 45 of the topic packet found at the following link on the CDC ICD–9–CM Web page at *http://www.cdc.gov/nchs/data/icd9/TopicpacketforMarch2011_HA1.pdf* for further information.

Shown in the table below are these proposed two diagnosis codes with their corresponding descriptions and their CC/MCC designations.

ICD–9–CM code	Code descriptor	CC/MCC designation
999.32	Bloodstream infection due to central venous catheter	CC
999.33	Local infection due to central venous catheter	CC

We are inviting public comments on the proposed adoption of these two ICD–9–CM diagnosis codes designated as CC/MCCs that are listed above, to be added to the Vascular Catheter-Associated Infection HAC category as indicated for FY 2013.

b. Proposal To Add New HAC Condition: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures

We discuss below our rationale for proposing a new condition, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures, for selection for FY 2013 as a HAC under section 1886(d)(4)(D) of the Act. As described in more detail in section II.F.1. of this preamble, each HAC must be: (1) High cost, high volume, or both; (2) assigned to a higher paying MS–DRG when present as a secondary diagnosis (that is, conditions under the MS–DRG system that are CCs or MCCs); and (3) could reasonably have been prevented through the application of evidence-based guidelines. We also discuss other considerations relating to the selection of a HAC, including any

administrative or operational issues associated with a proposed condition. For example, the condition may only be able to be identified by multiple codes, thereby requiring the development of special GROUPER logic to also exclude similar or related ICD–9–CM codes from being classified as a CC or an MCC. Similarly, a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable. We are inviting public comment on the degree to which these conditions fulfill these statutory requirements, as well as clinical, coding, and prevention issues on our proposal to add Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures as a condition subject to the HAC payment provision for discharges occurring on or after October 1, 2012.

CIED therapy reduces morbidity and mortality in selected patients with cardiac rhythm disturbances.[1] More than 500,000 CIEDs are implanted each year in the United States and 70 percent of CIED recipients are age 65 or older.[2] However, this benefit with regard to the treatment of cardiac rhythm disturbances is somewhat reduced by complications following device placement, including infections. Patients can present with early or late infections because of CIED placement.[3] Two-thirds of these infections are caused by Staphylococcus aureus and coagulase-negative Staphylococcus species. Treatment of these infections usually entails surgical explantation of the device, sometimes under general anesthesia and a prolonged course of intravenous antibiotics, along with external electrical support in a monitored intensive care setting. The rate of CIED infection is increasing faster than the rate of CIED implantation,[4] and there are published data on the mortality and cost associated with CIED infection or the relationship of these outcomes to different CIED types.

There is not a unique code that identifies SSI Following CIED Procedures. However, the condition can be identified as a subset of discharges with ICD–9–CM diagnosis code 996.61 (Infection and inflammatory reaction due to cardiac device, implant and graft) or 998.59 (Other postoperative infection). Our clinical advisors believe that diagnosis code 996.61 or 998.59, in combination with the associated procedure codes below, can accurately identify SSI Following CIED Procedures. The procedure codes are:

- 00.50 (Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system [CRT–P]);
- 00.51 (Implantation of cardiac resynchronization defibrillator, total system [CRT–D]);
- 00.52 (Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system);
- 00.53 (Implantation or replacement of cardiac resynchronization pacemaker pulse generator only [CRT–P]);
- 00.54 (Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only [CRT–D]);
- 37.80 (Insertion of permanent pacemaker, initial or replacement, type of device not specified);
- 37.81 (Initial insertion of single-chamber device, not specified as rate responsive);
- 37.82 (Initial insertion of single-chamber device, rate responsive);
- 37.83 (Initial insertion of dual-chamber device);
- 37.85 (Replacement of any type pacemaker device with single-chamber device, not specified as rate responsive);
- 37.86 (Replacement of any type of pacemaker device with single-chamber device, rate responsive);
- 37.87 (Replacement of any type pacemaker device with dual-chamber device);
- 37.94 (Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]);
- 37.96 (Implantation of automatic cardioverter/defibrillator pulse generator only);
- 37.98 (Replacement of automatic cardioverter/defibrillator pulse generator only);
- 37.74 (Insertion or replacement of epicardial lead [electrode] into epicardium);
- 37.75 (Revision of lead [electrode]);
- 37.76 (Replacement of transvenous atrial and/or ventricular lead(s) [electrode]);
- 37.77 (Removal of lead(s) [electrode] without replacement);
- 37.79 (Revision or relocation of cardiac device pocket); and
- 37.89 (Revision or removal of pacemaker device).

We are proposing to identify Surgical Site Infection Following CIED Procedures with diagnosis code 996.61 or 998.59 in combination with one or more of the above associated procedure codes. We believe the condition meets the three criteria for inclusion on the HAC list, as discussed in greater detail below.

First, the condition is one that is high cost and high volume. We reviewed Medicare claims data in the FY 2011 MedPAR file. For FY 2011, we found that there were 859 inpatient discharges coded with Surgical Site Infection Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims. The cases had an average cost of $51,795 for the entire hospital stay. We found that there were 583 inpatient discharges coded with Surgical Site Infection Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims reported as POA. These POA cases had an average cost of $41,999. We also found that there were 276 inpatient discharges coded with Surgical Site Infection Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims reported as NPOA. These NPOA cases had an average cost of $72,485. We note that these data are consistent with other data presented for current HACs. Therefore, we believe this condition is high cost and high volume.

In addition, we reviewed the literature regarding this condition. Infection associated with CIED procedures resulted in a substantial incremental increase in admission mortality and long-term mortality, and varies with the type of CIED. For the purposes of this proposal, we are considering CIED procedures in the

[1] Epstein, A. E., J. P. DiMarco, *et al.* (2008). ''ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons.'' *Circulation* 117(21): e350–408.

[2] Zhan, C., W. B. Baine, *et al.* (2007). ''Cardiac device implantation in the United States from 1997 through 2004: a population-based analysis.'' *J Gen Intern Med,* 23 Suppl 1: 13–19.

[3] Baddour, L. M., A. E. Epstein, *et al.* (2010). ''Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association.'' *Circulation,* 121(20048212): 458–477.

Baddour, L. M., A. E. Epstein, *et al.* (2010). ''Update on Cardiovascular Implantable Electronic Device Infections and Their Management: A Scientific Statement From the American Heart Association.'' *Circulation,* 121(3): 458–477.

[4] Greenspon, A. J., J. D. Patel, *et al.* (2011). ''16–Year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators in the United States 1993 to 2008.'' *Journal of the American College of Cardiology* 58(10): 1001–1006.

aggregate. Several large studies showed CIED infection associated with an approximately 5 percent to 8 percent inhospital mortality as well as a 17.5 percent to 35.1 percent one year mortality.[5] Additionally, there is a significant cost impact for patients who suffer infections after CIED implantation. A recent large analysis of 2007 data on over 200,000 Medicare beneficiaries demonstrated the mean hospital cost of CIED infections to be $28,676 to $53,349, compared with a mean hospital cost ranging from $12,468 to $36,851 for beneficiaries without infection.[6] This additional information supports our conclusion from our analysis of data in the MedPAR file that this condition is high cost.

Second, the condition of Surgical Site Infection Following CIED Procedures, as specified in our proposal, is a CC under the MS–DRG system. We have not identified any additional administrative or operational difficulties associated with proposing this condition as a HAC.

Third, because there are widely recognized guidelines for the prevention of Surgical Site Infection Following CIED Procedures, we believe the condition is reasonably preventable through application of evidenced-based guidelines. A large randomized controlled trial demonstrated that prophylactic preoperative antibiotics reduced CIED infection by 81 percent in patients who received them.[7] Well-accepted guidelines for the prevention and prophylaxis of CIED infection now exist supporting the use of prophylactic antibiotics.

We are inviting public comment on whether Surgical Site Infection Following CIED Procedures meets the requirements set forth under section 1886(d)(4)(D) of the Act, as well as other coding and prevention issues associated with our proposal to add this condition as a proposed condition subject to the HAC payment provision for FY 2013 (for discharges occurring on or after October 1, 2012). We are particularly interested in receiving comments on the degree to which Surgical Site Infection Following CIED Procedures is reasonably preventable through the application of evidence-based guidelines.

c. Proposal To Add New HAC: Iatrogenic Pneumothorax With Venous Catheterization

We discuss below our rationale for proposing a new condition, Iatrogenic Pneumothorax with Venous Catheterization, for selection as a HAC for FY 2013 under section 1886(d)(4)(D) of the Act. We had previously proposed Iatrogenic Pneumothorax more generally as a HAC in the FY 2009 IPPS rulemaking (73 FR 48485).

In the FY 2009 IPPS final rule (73 FR 48485), we considered Iatrogenic Pneumothorax as a condition but did not finalize it due to commenters' concerns about the preventability of the condition when following the evidence-based guidelines. Most commenters opposed the selection of Iatrogenic Pneumothorax as a HAC and indicated that the evidence-based guidelines often acknowledge that Iatrogenic Pneumothorax is a known relatively common risk for certain procedures. Further, with regard to evidence-based guidelines, many commenters opposed designation of this condition as a HAC due to a lack of consensus within the medical community regarding its preventability.[8] Some commenters offered suggestions to exclude certain procedures or situations, including central line placement, thoracotomy, and the use of a ventilator, if Iatrogenic Pneumothorax were to be selected as a HAC. In that rule, we noted that we would continue to review the development of evidence-based guidelines for the prevention of Iatrogenic Pneumothorax if evidence warrants and consider Iatrogenic Pneumothorax as a HAC in the future. We refer readers to that final rule for a more detailed discussion (73 FR 48485). To address concerns raised by commenters in FY 2009, we reviewed changes in the standard of care and evidence-based guidelines to identify specific situations where Iatrogenic Pneumothorax would be considered reasonably preventable and identified venous catheterization as one such instance.

Pneumothorax is defined as the presence of air or gas in the pleural cavity, which is the space between the covering of the tissue of the lung and parietal pleura, or the part of the pleura that lines the chest wall. The presence of air in this space partially or completely collapses the lung and is life threatening. Air can enter the intrapleural space through a passage through the chest wall. Iatrogenic Pneumothorax is a type of traumatic pneumothorax that results from incursion into the pleural space secondary to diagnostic or therapeutic medical intervention, such as needle placement for central line catheter guidance.

There is no unique code that identifies Iatrogenic Pneumothorax with Venous Catheterization. However, Iatrogenic Pneumothorax with Venous Catheterization can be identified as a subset of discharges with ICD–9–CM diagnosis code 512.1 (Iatrogenic pneumothorax). Our clinical advisors believe that diagnosis code 512.1, in combination with the associated procedure code 38.93 (Venous catheterization NEC), can accurately identify Iatrogenic Pneumothorax with Venous Catheterization. We are proposing to identify Iatrogenic Pneumothorax with Venous Catheterization reported in combination with diagnosis code 512.1 (Iatrogenic pneumothorax) and procedure code 38.93 (Venous catheterization NEC). We recognize that, in quality measurement such as with the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) Number 6 (Iatrogenic Pneumothorax Rate), exclusion criteria are used to increase the accuracy of identifying these cases. We believe that, by limiting our proposal to include Iatrogenic Pneumothorax as a HAC only in the context of venous catheterization, we have improved our ability to accurately identify these cases. While we are not proposing exclusion criteria, we welcome public comment in this regard. In addition, we believe this more narrowly tailored condition meets the three criteria for inclusion on the HAC list, as discussed in greater detail below.

First, the condition is one that is high cost and high volume. We reviewed Medicare claims data in the FY 2011 MedPAR file. We found that there were 4,467 inpatient discharge cases coded for Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93. The cases had an average cost of $39,128 for the entire hospital stay. We found that there were 612 inpatient discharge cases coded for Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93 submitted through Medicare claims reported as POA. These POA cases had an average cost of $26,693. We also found that there were 3,855 inpatient discharge cases coded for

[5] Tarakji, K. G., E. J. Chan, *et al.* (2010). ''Cardiac implantable electronic device infections: Presentation, management, and patient outcomes.'' *Heart Rhythm* 7(8): 1043–1047.

[6] Sohail, M. R., C. A. Henrikson, *et al.* (2011). ''Mortality and cost associated with cardiovascular implantable electronic device infections.'' *Arch Intern Med* 171(20): 1821–1828.

[7] de Oliveira, J. C., M. Martinelli, *et al.* (2009). ''Efficacy of Antibiotic Prophylaxis Before the Implantation of Pacemakers and Cardioverter-Defibrillators: Results of a Large, Prospective, Randomized, Double-Blinded, Placebo-Controlled Trial.'' *Circ Arrhythm Electrophysiol,* 2(1): 29–34.

[8] Ahan, *et al.* ''Accidental Iatrogenic Pneumothorax in Hospitalized Patients,'' *Medical Care,* 44(2):182–6, Feb. 2006.

Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93 submitted through Medicare claims reported as NPOA. These NPOA cases had an average cost of $41,102. We note that these data are consistent with other data presented for current HACs. Therefore, we believe this condition is high cost and high volume.

In addition, we reviewed the literature regarding this condition. The cannulation of veins (that is insertion of a catheter) with central venous catheterization is an important aspect of patient care for the administration of fluids and medications and for monitoring purposes. Eight percent of hospitalized patients receive a central venous catheter, and more than 5 million central venous catheters are inserted in the United States each year. Indwelling catheters have several known complications and side effects associated with their use, such as infections or vessel damage. Additionally, there are risks associated with the placement of central venous catheters including the risk of pneumothorax for central catheters placed in the upper area of the patient's neck or chest when placed in the internal jugular or subclavian veins. Mechanical complications associated with Iatrogenic Pneumothorax are reported to occur in 5 to 19 percent of patients.[9]

Second, the condition of Iatrogenic Pneumothorax with Venous Catheterization as specified in our proposal is a CC under the MS–DRGs.

Third, there are widely recognized guidelines that address the prevention of Iatrogenic Pneumothorax with Venous Catheterization, and we believe that Iatrogenic Pneumothorax in the context of venous catheterization is reasonably preventable through application of these evidenced-based guidelines.

In terms of guidelines, the AHRQ, in a 2001 report ''Making Health Care Safer: A Critical Analysis of Patient Safety Practices'' (AHRQ Publication No. 01–EO58) recommended the use of ultrasound for the placement of all central venous catheters as one of its 11 practices aimed at improving patient care. Current standard placement techniques for these venous catheters rely on the knowledge of anatomic landmarks and other indicators to guide the initial cannulation of the vein. The increase in the number of small, advanced and portable 2D ultrasound devices has inspired the use of these newer ultrasound devices in central venous line placement, as now direct visualization of the target vessel can be achieved, making it easier to avoid these complications. Recommendations for the use of ultrasound as an adjunct to central venous line placement now exist and are based on supportive literature Category A (Randomized controlled trials report statistically significant (P _ .01) differences between clinical interventions for a specified clinical outcome) with a Level 1 weight of scientific evidence (multiple randomized controlled trials with the aggregated findings supported by meta-analysis).[10] Several studies have shown a decrease in the mechanical complication rate with the use of ultrasound during line placement.[11] Guidelines for performing ultrasound guided vascular cannulation have been recently published.[12]

We believe new evidence-based guidelines provide substantial clinical guidance for reasonable prevention when this condition occurs in the context of venous catheterization. We are inviting public comment on whether Iatrogenic Pneumothorax with Venous Catheterization meets the requirements set forth under section 1886(d)(4)(D) of the Act, as well as other coding and prevention issues associated with our proposal to add this proposed condition, as a condition subject to the HAC payment provision for discharges occurring on or after October 1, 2012. We are particularly interested in public comment on how limiting the condition to situations in which it occurs in conjunction with venous catheterization influences preventability, and whether additional limits should be considered in the context of venous catheterization.

With the exception of the condition of Iatrogenic Pneumothorax with Venous Catheterization, at this time, we do not believe that additional analysis exists that would require us to change our previous determinations regarding the previously considered candidate HACs in the FY 2008 IPPS final rule with comment period (72 FR 47200 through 47218), the FY 2009 IPPS final rule (73 FR 48471 through 48491), the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782 through 43785), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51510 through 51511). We refer readers to these rules for a detailed discussion that supports our determination regarding each of the previously considered candidate HACs and continue to encourage public dialogue about refinements to the HAC list.

6. RTI Program Evaluation Summary

On September 30, 2009, a contract was awarded to Research Triangle Institute, International (RTI) to evaluate the impact of the Hospital-Acquired Condition—Present on Admission (HAC–POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. This is an intra-agency project with funding and technical support coming from CMS, OPHS, AHRQ, and CDC. The evaluation will also examine the implementation of the program and evaluate additional conditions for future selection.

RTI's evaluation of the HAC–POA provisions is divided into several parts. The evaluation includes conditions that are currently treated as HACs and also previously considered candidate conditions. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (50085 through 50101), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51512 through 51522) for a fuller description of this evaluation and findings to date regarding analysis of FY 2009 and FY 2010 data, respectively. Summary and detailed data were made publicly available on the CMS Web site at: *http://www.cms.gov/HospitalAcqCond/01_Overview.asp* and the RTI Web site at: *http://www.rti.org/reports/cms/*. RTI's analysis of the FY 2011 MedPAR data file for the HAC–POA program evaluation is being prepared for the FY 2013 IPPS/LTCH PPS final rule. When these summary and detailed data are available, they also will be made publicly available on the two Web sites noted above.

In addition to the evaluation of HAC and POA MedPAR claims data, RTI has also conducted analyses on readmissions due to HACs and the incremental costs of HACs to the health care system, a study of spillover effects and unintended consequences, as well

[9] McGee, D. C. and M. K. Gould (2003). ''Preventing Complications of Central Venous Catheterization.'' *New England Journal of Medicine,* 348(12): 1123–1133.

[10] Echoc, A., U. R., B. T., A. S., O. A., A. T., S. O., C. A., T. F., O. T. (2010). ''Practice Guidelines for Perioperative Transesophageal Echocardiography.'' *Anesthesiology,* 112(5): 1084–1096 1010.1097/ALN.1080b1013e3181c1051e1090.

[11] Hind, D.: ''Ultrasonic device for central venous cannulation: Meta-analysis.'' BJM, 2003, vol. 327, 7411:361–364; and

Troianos, C. A., G. S. Hartman, *et al.* (2012). ''Guidelines for Performing Ultrasound Guided Vascular Cannulation: Recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists.'' *Anesthesia and Analgesia,* 114(1): 46–72.

[12] Troianos, C. A., G. S. Hartman, *et al.* (2012). ''Guidelines for Performing Ultrasound Guided Vascular Cannulation: Recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists.'' *Anesthesia and Analgesia,* 114(1): 46–72.

as an updated analysis of the evidence-based guidelines for selected and previously considered HACs. Reports on these analyses have been made publicly available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html*.

G. Proposed Changes to Specific MS–DRG Classifications

In this FY 2013 IPPS/LTCH PPS proposed rule, we are inviting public comment on each of the MS–DRG classification proposed changes described below, as well as our proposals to maintain certain existing MS–DRG classifications, which are also discussed below. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS–DRG classification based on our analysis of claims data.

We encourage input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2013, comments and suggestions should have been submitted by early December 2011. The comments that were submitted in a timely manner are discussed below in this section.

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Ventricular Assist Devices (VADs)

A ventricular assist device (VAD) is a mechanical circulatory device or pump that is used to partially or completely support heart function and blood flow in patients with a damaged or weakened heart. The device takes blood from the ventricles of the heart and helps pump the blood to the rest of the body.

Some VADs are intended for short-term use, often for patients who are recovering from heart attacks or heart surgery, while other VADs are intended for long-term use (months to years and, in some cases, for life). VADs are not the same device as artificial hearts, which are designed to completely take over cardiac function and generally require the removal of the patient's native heart.

VADs are designed to assist the ventricles, either the right (RVAD) or the left (LVAD), and, in some cases, both ventricles at once (BiVAD). The type of VAD used depends on the patient's underlying heart disease and the pulmonary arterial resistance that determines the load on the right ventricle. LVADs are the most commonly used, but when pulmonary arterial resistance is high, right ventricular assistance becomes necessary and an RVAD may be inserted. Long-term VADs are normally used to help maintain a patient's quality of life while he or she awaits a heart transplant. This process is known as a ''bridge to transplant.'' However, sometimes the insertion of an LVAD becomes the final treatment for the patient, which is known as ''destination therapy.'' In this case, the VAD is a permanent implant, and no heart transplantation occurs. In a smaller number of cases, the implantation of a VAD, combined with pharmaceutical therapy, has enabled the native heart to recover sufficiently to allow the VAD to be explanted, a ''bridge to recovery.''

We have issued a national coverage determination (NCD) entitled ''Artificial Hearts and Related Devices'' under Section 20.9 of the Medicare Coverage Manual (Pub. No. 100–3). This NCD, which describes CMS' requirements for coverage of medical services provided to Medicare beneficiaries for the insertion of VADs, can be found at the CMS Web site at: *https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=5&NCAId=211&ver=20&NcaName=Artificial+Hearts&bc=ACAAAAAAIAAA&*. We refer readers to this Web site for the complete viewing of the NCD for the insertion of VADs.

The assignment of procedure codes used to describe the insertion of VADs has been discussed repeatedly in IPPS rulemaking, for the CMS–DRGs (in effect prior to FY 2008) and more recently for the MS–DRGs (FY 2008 to present). We refer readers to the FY 2003 IPPS final rule (67 FR 49989) for a complete discussion of the assignment of these procedure codes up to that date. In addition, the topic was discussed in FY 2005; we refer readers to the FY 2005 IPPS final rule (69 FR 48927 through 48930) for a complete discussion regarding the assignment of these procedure codes for FY 2005. Specifically, for FY 2005, we moved ICD–9–CM procedure code 37.66 (Insertion of implantable heart assist system) from CMS–DRG 525 (Other Heart Assist System Implant) to CMS–DRG 103 (Heart Transplant). When we adopted the MS–DRG classification system in FY 2008, former CMS–DRG 103 remained in the Pre-MDC section but was renamed and subdivided into MS–DRG 001 (Heart Transplant or Implant of Heart Assist System with MCC) and MS–DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC).

For FY 2013, we have received a request to restructure MS–DRGs 001 and 002 by removing all of the procedure codes that describe the insertion of a device, leaving only procedure codes 33.6 (Combined heart-lung transplantation) and 37.51 (Heart transplantation) in the heart transplant DRGs. The requestor further asked that the remaining device codes be assigned to newly created MS–DRGs. The requestor believed that, within the existing MS–DRG grouping, CMS is underpaying for services to patients who have a VAD implanted and overpaying for services to patients who have heart transplantations. The requestor believed that the recommended restructuring ''would allow defined grouping of cases with the higher level of resource [sic] required reflected in payment.''

We have reviewed data in the September 2011 update of the FY 2011 MedPAR file and found that the average length of stay for heart transplantations and VAD implantation cases are very similar (35.1 days for heart transplantations and 36.63 days for VAD implantations). We also found that the average cost for VAD implantation cases alone is higher than the average cost of heart transplantation cases. The table below includes our findings.

MS–DRG	Number of cases	Average length of stay	Average cost
MS–DRG 001—All Cases	1,235	36.97	$164,846
MS–DRG 001—Cases with Heart Transplant without VAD	384	35.1	123,472
MS–DRG 001—Cases with VAD Insertion Alone	811	36.85	181,915
MS–DRG 002—All Cases	313	19.66	89,818
MS–DRG 002—Cases with Heart Transplant without VAD	172	15.1	58,890
MS–DRG 002—Cases with VAD Insertion Alone	140	25.31	128,069

We believe that this higher average cost could be attributable to the cost of the device itself. There are very few VADs approved by FDA; therefore, we believe this small group of manufacturers is able to set their own charges in the market. We point out that the IPPS is not designed to pay solely for the cost of devices. The MS–DRG classification system (and more importantly, the IPPS) is not based solely on the cost of devices.

Rather, the MS–DRG system is a patient classification system that provides an average means of relating the type of patients a hospital treats (that is, case-mix) to the costs incurred by the hospital. We have previously stated that, ''Central to the success of the Medicare inpatient hospital prospective payment system is that DRGs have remained a clinical description of why the patient required hospitalization. We believe it would be undesirable to transform DRGs into detailed descriptions of the technology and processes used by the hospital to treat the patient. If such a transformation were to happen, the DRGs would become largely a repackaging of fee-for-service without the management and communication benefits. The separation of the clinical and payment weight methodologies allows a stable clinical methodology to be maintained, while the payment weights evolve in response to changing practice patterns. The packaging of all services associated with the care of a particular type of patient into a single payment amount provides the incentive for efficiency inherent in a DRG-based prospective payment system. Substantial disaggregation of the DRGs into smaller units of payment, or a substantial number of cases receiving extra payments, would undermine the incentives and communication value in the DRG system.'' (66 FR 46904)

The results of our review of the claims data for MS–DRGs 001 and 002 are summarized in the following table.

Code	Description of code(s)	Number of cases
MS–DRG 001 (Heart Transplant or Implant of Heart Assist System With MCC)		
All codes		1,235
33.6 or 37.51	Combined heart-lung transplantation or Heart transplantation	384
33.6 or 37.51 with 37.66	Combined heart-lung transplantation or Heart transplantation with Insertion of implantable heart assist system (VAD).	11
37.52	Implantation of total internal biventricular heart replacement system (Artificial heart)	2
37.66	Insertion of implantable heart assist system (VAD)	811
37.60 with 37.64	Implantation or insertion of biventricular external heart assist system + Removal of external heart assist system(s) or device(s).	1
37.63 with 37.64	Repair of heart assist system + Removal of external heart assist system(s) or device(s)	0
37.64 with 37.65	Removal of external heart assist system(s) or device(s) + plant of single ventricular (extracorporeal) external heart assist system.	22
	Multiple VADs without heart transplant	22
MS–DRG 002 (Heart Transplant or Implant of Heart Assist System With MCC)		
All codes		313
33.6 or 37.51	Combined heart-lung transplantation or Heart transplantation	172
33.6 or 37.51 with 37.66	Combined heart-lung transplantation or Heart transplantation with Insertion of implantable heart assist system (VAD).	0
37.52	Implantation of total internal biventricular heart replacement system (Artificial heart)	0
37.66	Insertion of implantable heart assist system (VAD)	140
37.60 with 37.64	Implantation or insertion of biventricular external heart assist system plus Removal of external heart assist system(s) or device(s).	0
37.63 with 37.64	Repair of heart assist system + Removal of external heart assist system(s) or device(s)	0
37.64 with 37.65	Removal of external heart assist system(s) or device(s) + plant of single ventricular (extracorporeal) external heart assist system.	1
	Multiple VADs without heart transplant	4

In general, we believe that the IPPS should accurately recognize differences in utilization for clinically distinct procedures. However, we also reiterate the language in the FY 2009 IPPS final rule that the payments under a prospective payment system are predicated on averages (73 FR 48443). To create a new MS–DRG specific to VAD implantation would require basing that MS–DRG almost exclusively on the presence of procedure code 37.66, representing a single procedure and currently one manufacturer with FDA approval. Currently, other manufacturers are reported to be in clinical trials with their VADs. This approach negates our longstanding method of grouping like procedures and diminishes the concept of averaging. Further, we are concerned that ignoring the structure of the MS–DRG system solely for the purpose of increasing payment for one device would set an unwarranted precedent for defining all of the other MS–DRGs in the system (73 FR 48497 and 48498).

The commenter requested that we create two new MS–DRGs for the VADs and that the requested MS–DRGs be divided based on the presence or absence of an MCC. We point out that the final rule establishing the MS–DRGs sets forth five criteria, all five of which are required to be met in order to warrant creation of a CC or an MCC subgroup within a base MS–DRG. The criteria can be found in the FY 2008 IPPS final rule with comment period (72 FR 47169). The original criteria were based on average charges; we now use average costs (FY 2007 IPPS final rule (71 FR 47882)). To reiterate, these criteria are as follows:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.

• There is a $2,000 difference in average cost between subgroups.

As procedure code 37.66 predominates in our claims data for VAD implantations, we are including the following table demonstrating the cost difference between MS–DRG 001 and MS–DRG 002.

MS–DRG	Number of cases	Average cost
001—Cases with procedure code 37.66	811	$181,915
002—Cases with procedure code 37.66	140	128,069

As stated in the FY 2008 IPPS final rule with comment period, all five criteria must be met in order to subdivide an MS–DRG into MCC and non-MCC severity levels. In this instance, the number of cases in MS–DRG 002 containing procedure code 37.66 is 140, not the minimum number of 500 cases as established by the MS–DRG severity criteria. Therefore, even if we were to create a new MS–DRG for VAD implantation, unless we further divided the MS–DRG based on the presence of an MCC, we would substantially overpay approximately 15 percent of total VAD cases. However, we could not create multiple MS–DRGs for VAD implantation without ignoring our rules for subdividing MS–DRGs.

For these reasons, for FY 2013, we are not proposing to make any changes to the structure of MS–DRGs 001 and 002. We are inviting public comment on our proposal.

b. Allogeneic Bone Marrow Transplant

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50101), we deleted MS–DRG 009 (Bone Marrow Transplant) and created two new MS–DRGs: MS–DRG 014 (Allogeneic Bone Marrow Transplant) and MS–DRG 015 (Autologous Bone Marrow Transplant). We created MS–DRGs 014 and 015 because of differences in costs associated with the procedures in these two MS–DRGs. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51525 through 51526), we further subdivided MS–DRG 015 into two severity levels, by deleting MS–DRG 015 and creating MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC); and MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC). We created MS–DRGs 014 and 015 as these groups meet all five criteria for subdivision by severity level that we established in the FY 2008 IPPS final rule with comment period (72 FR 47169). As we discussed in the FY 2012 IPPS/LTCH PPS final rule, MS–DRG 014 did not meet the criteria for subdivision by severity level.

During the comment period for the FY 2012 IPPS/LTCH PPS proposed rule, we received a public comment regarding related and unrelated allogeneic bone marrow transplants (which are captured in MS–DRG 014) that had not been the subject of a proposal in that proposed rule. This issue was referred to briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), but we did not address the issue because we considered the comment to be out of the scope of provisions of the proposed rule. However, we are addressing this issue in this FY 2013 proposed rule. The commenter recommended that MS–DRG 014 be subdivided into two MS–DRGs based on related and unrelated transplant donor source.

Allogeneic bone marrow transplantation utilizes the bone marrow or stem cells from a donor that is either related (sibling or other close family member) or unrelated (not a close family member of the recipient) in the treatment of certain cancers and bone marrow diseases. Allogeneic transplant recipients must have a tissue type that matches the donor. According to the commenter, a related donor will typically be managed by the transplant facility from human leukocyte antigen (HLA) molecular typing through mobilization and collection, while an unrelated donor requires the use of donor registry for searching and collection process. According to the commenter, the unrelated donor setting adds significant costs to the transplant that would not be incurred in the related transplant setting.

Currently, there are three ICD–9–CM procedure codes that identify the transplant donor source:

• 00.91 (Transplant from live related donor)
• 00.92 (Transplant from live non-related donor)
• 00.93 (Transplant from cadaver)

In our analysis of data in the FY 2011 MedPAR file, we found 467 cases assigned to MS–DRG 014 with average costs of approximately $64,403 and an average length of stay of approximately 24.8 days. There were 125 cases that reported procedure code 00.91 on the claim as the related transplant donor source with average costs of approximately $55,969 and an average length of stay of approximately 24.1 days. In our analysis of the unrelated donor source, we included the cases reported with the transplant from a cadaver donor source (code 00.93) with the transplant from a live nonrelated donor source (code 00.92). There were 213 cases that reported either code 00.92 or 00.93 as the transplant donor source with average costs of approximately $64,837 and an average length of stay of approximately 23 days. There were 129 cases that did not report a transplant donor source with average costs of approximately $71,859 and an average length of stay of approximately 28.5 days. The following table illustrates our findings:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 014—All cases	467	24.8	$64,403
MS–DRG 014—Live related donor (code 00.91)	125	24.1	55,969
MS–DRG 014—Live nonrelated donor (code 00.92) or cadaver (code 00.93)	213	23	64,837
MS–DRG 014—No donor source	129	28.5	71,859

We note that one quarter of the cases (129 out of 467 cases) that did not report a transplant donor source code had the highest average costs of approximately $71,859, compared to $55,969 for live related donors and $64,837 for live nonrelated or cadaver donors and $64,403 for the overall average cost of cases within MS–DRG 014. The cases without a transplant donor source code also had a longer length of stay (28.5 days) than the live-related donor cases

(24.1 days), the live nonrelated or cadaver cases (23 days), and the overall cases (24.8 days) assigned to MS–DRG 014.

Based on these findings, we believe that it would not be advisable to include cases without a transplant donor source code with the live nonrelated or cadaver donor cases, as we believe it would encourage providers not to report the transplant donor source code. All possible options must be included in any MS–DRG reconfiguration. Therefore, cases with no reported transplant donor source code must be included in the updated logic because this is the group with the highest average costs. Our clinical advisors reviewed this issue and do not support splitting MS–DRG 014 into two MS–DRGs because a quarter of the cases did not provide a transplant donor source. Therefore, we have concluded that the cases reported with a transplant donor source code are appropriately assigned to MS–DRG 014 and that MS–DRG does not warrant further subdivision. Without more complete information on donor source, we are not proposing that MS–DRG 014 be subdivided at this time. We are inviting public comment on our proposal not to subdivide MS–DRG 014 into two MS–DRGs based on related and unrelated donor source.

2. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat): Influenza With Pneumonia

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), we discussed a public comment that we considered out of the scope of the FY 2012 proposed rule. Therefore, we did not address the issues in the final rule. The commenter requested that we consider reassigning cases with a combined diagnosis of influenza with pneumonia from a set of simple pneumonia MS–DRGs to a set of MS–DRGs that captures a more severe type of pneumonia. The specific request involves cases now assigned to MS–DRGs 193 (Simple Pneumonia and Pleurisy with MCC), 194 (Simple Pneumonia and Pleurisy with CC), and 195 (Simple Pneumonia and Pleurisy without MCC/CC) being moved to MS–DRGs 177 (Respiratory Infections and Inflammations with MCC), 178 (Respiratory Infections and Inflammations with CC), and 179 (Respiratory Infections and Inflammations without MCC/CC).

We examined data in the FY 2011 MedPAR file on cases that reported diagnosis code 487.0 (Influenza with pneumonia) as the principal diagnosis with an additional secondary diagnosis code for one of the following types of pneumonia:

- 482.0 (Pneumonia due to Klebsiella pneumoniae)
- 482.1 (Pneumonia due to Pseudomonas)
- 482.40 (Pneumonia due to Staphylococcus, unspecified)
- 482.41 (Methicillin susceptible pneumonia due to Staphylococcus aureus)
- 482.42 (Methicillin resistant pneumonia due to Staphylococcus aureus)
- 482.49 (Other Staphylococcus pneumonia)
- 482.81 (Pneumonia due to anaerobes)
- 482.82 (Pneumonia due to Escherichia coli [E. coli])
- 482.83 (Pneumonia due to other gram-negative bacteria)
- 482.84 (Pneumonia due to Legionnaires' disease)
- 482.89 (Pneumonia due to other specified bacteria)

Currently, when one of the pneumonia codes listed above is reported as a principal diagnosis, the case is assigned to MS–DRG 177, 178, or 179. However, when the patient has been diagnosed with one of these types of pneumonia and also has influenza, the ICD–9–CM coding book directs the coder to report diagnosis code 487.0 as the principal diagnosis and to assign an additional secondary code to describe the specific type of pneumonia. This reporting results in cases with diagnoses of both influenza and specific types of pneumonia being assigned to MS–DRG 193, 194, or 195 (Simple Pneumonia and Pleurisy with MCC, with CC, or without CC/MCC, respectively), instead of MS–DRG 177, 178, or 179. The commenter requested that we reassign cases reporting code 487.0 as the principal diagnosis with one of the specific pneumonia codes listed above as a secondary diagnosis to MS–DRGs 177, 178, and 179.

We analyzed data from the MedPAR file on cases with patients with pneumonia and found the following:

MS–DRG	Number of cases	Average length of stay	Average cost
MS–DRG 177—All cases	69,128	8.20	$13,002
MS–DRG 178—All cases	59,559	6.40	9,193
MS–DRG 179—All cases	14,108	4.65	6,365
MS–DRG 193—All cases	125,892	6.28	9,589
MS–DRG 193—Cases with principal diagnosis code 487.0 and with a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	57	9.3	15,867
MS–DRG 193—Cases with principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	1,320	6.93	10,416
MS–DRG 194—All cases	191,030	4.73	6,524
MS–DRG 194—Cases with principal diagnosis code 487.0 and with a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	59	6.9	9,752
MS–DRG 194—Principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	2,088	5.16	6,871
MS–DRG 195—All cases	80,253	3.53	4,660
MS–DRG 195—Cases with a principal diagnosis code 487.0 and a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	12	4.8	5,842
MS–DRG 195—Cases with principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	1,065	3.78	4,580

The data showed that cases reporting a principal diagnosis code 487.0 with one of the pneumonia codes listed above as a secondary diagnosis have significantly higher average costs ($15,867 in MS–DRG 193, $9,752 in MS–DRG 194, and $5,842 in MS–DRG 195) than those cases reported without one of the pneumonia codes listed above as a secondary diagnosis ($10,416 in MS–DRG 193, $6,871 in MS–DRG 194, and $4,580 in MS–DRG 195), and also the overall average costs for all cases in MS–DRGs 193, 194, and 195 ($9,589, $6,524, and $4,660, respectively). The influenza and pneumonia cases had average costs that more closely align with the average costs of cases currently assigned to MS–DRGs 177, 178, and 179 ($13,002, $9,193, and $6,365, respectively).

As a result of our analysis, the data support the commenter's request that we reassign cases reporting a principal diagnosis code 487.0 and an additional secondary diagnosis code for one of the pneumonia codes listed above, from MS–DRGs 193, 194, and 195 to MS–DRGs 177, 178, and 179. Our clinical advisors also support reassigning these cases to MS–DRGs 177, 178, and 179. Therefore, for FY 2013, we are proposing to reassign cases with a principal diagnosis code 487.0 and an additional secondary diagnosis code of one of the following pneumonia codes listed as a secondary diagnosis codes from MS–DRGs 193, 194, and 195 to MS–DRGs 177, 178, and 179: 482.0; 482.1; 482.40; 482.41; 482.42; 482.49; 482.81; 482.82; 482.83; 482.84; and 482.89.

We are inviting public comment on our proposal for FY 2013.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Mitral Valve Repair With Implant

We received a request to reassign procedure code 35.97 (Percutaneous mitral valve repair with implant) to the following MS–DRGs:

- MS–DRG 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with MCC);
- MS–DRG 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with CC);
- MS–DRG 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac without CC/MCC);
- MS–DRG 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with MCC);
- MS–DRG 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with CC); and
- MS–DRG 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac without CC/MCC).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51528 through 51529), we discussed reassigning procedure code 35.97 from MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively) and MS–DRGs 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents), 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC), 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents), 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC), 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC), and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI without MCC). In that final rule, we stated that we did not have sufficient claims data on which to base and evaluate any proposed changes to the current MS–DRG assignment. Procedure code 35.97 was created for use beginning October 1, 2010 (FY 2011) after the concept of percutaneous valve repair was presented at the March 2010 ICD–9–CM Coordination and Maintenance Committee meeting. Procedure code 35.97 was created at that time to describe the MitraClip™ device and any other percutaneous mitral valve repair devices currently on the market. This procedure code was assigned to the following MS–DRGs: 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively); 246 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 247 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent without MCC); 248 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with MCC or 4+ Vessels/Stents); 249 (Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent without MCC); 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with MCC); and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI without MCC).

According to the Food and Drug Administration's (FDA's) terms of the clinical trial for MitraClip™, the device is to be implanted in patients without any additional surgeries performed. Therefore, based on these terms, we stated that while the procedure code is assigned to MS–DRGs 246 through 251, the most likely MS–DRG assignments would be MS–DRGs 250 and 251, as described above. As we stated in the FY 2012 IPPS/LTCH PPS final rule, because procedure code 35.97 had only been in use since October 1, 2010, there were no claims data in the most recent update of the MedPAR file at that time to evaluate any alternative MS–DRG assignments. Therefore, we did not make any MS–DRG assignment changes for procedure code 35.97 for FY 2012.

For this proposed rule, we have analyzed claims data from the FY 2011 MedPAR file on the procedure that describes mitral valve repair with implant and found the following:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 216—All Cases	9,624	16.44	$61,015
MS–DRG 217—All Cases	5,655	10.24	41,324
MS–DRG 218—All Cases	995	7.43	34,587
MS–DRG 219—All Cases	15,336	12.53	50,176
MS–DRG 220—All Cases	18,455	7.53	34,150
MS–DRG 221—All Cases	4,719	5.59	29,082
MS–DRG 231—All Cases	1,170	12.17	49,728
MS–DRG 231—Cases with Procedure Code 35.97	4	13.75	35,409
MS–DRG 232—All Cases	1,010	9.16	37,820
MS–DRG 232—Cases with Procedure Code 35.97	9	13.56	46,008
MS–DRG 246—All Cases	29,299	5.20	20,725
MS–DRG 247—All Cases	109,661	2.39	13,014
MS–DRG 248—All Cases	13,562	6.35	19,785
MS–DRG 248—Cases with Procedure Code 35.97	1	32.00	110,262
MS–DRG 249—All Cases	35,100	2.86	11,806

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 250—All Cases	8,313	7.07	19,673
MS–DRG 250—Cases with Procedure Code 35.97	39	9.77	29,753
MS–DRG 251—All Cases	31,316	2.92	12,658
MS–DRG 251—Cases with Procedure Code 35.97	98	2.69	18,651

We note that most of the cases were found in MS–DRGs 250 and 251, as we predicted in the FY 2012 IPPS/LTCH PPS final rule based on FDA's terms of the clinical trial for MitraClip™. As stated earlier, the device is to be implanted in patients without any additional surgeries performed. There were 39 cases in MS–DRG 250 with average costs of $29,753 (which includes cases with an MCC). These average costs are significantly lower than the average costs of $61,015 for cases in MS–DRG 216, and the average costs of $50,176 for cases in MS–DRG 219 (which includes cases with an MCC). There were 98 cases in MS–DRG 251 (without MCC) with average costs of $18,651. These average costs also are lower than the average costs of comparable cases in MS–DRGs 217, 218, 220, and 221, whose average costs range from a high of $41,324 to a low of $29,082. While the average costs of mitral valve repair cases are higher than the average costs of other cases assigned to MS–DRGs 250 and 251, they are significantly less than the average costs of cardiac valve replacement cases assigned to MS–DRGs 216 through 221. Our analysis of the claims data does not support reassigning the procedure that describes percutaneous mitral valve repair with implant from MS–DRGs 250 and 251 to MS–DRGs 216 through 221. Our clinical advisors also support maintaining the current assignment of this procedure in MS–DRGs 250 and 251. Therefore, based on our findings, we are not proposing to reassign procedure code 35.97 from MS–DRGs 250 and 251 to MS–DRGs 216 through 221.

We are inviting public comment on our proposal to maintain the current assignment of procedure code 35.97 in MS–DRGs 250 and 251 and not to reassign the procedure code to MS–DRGs 217 through 221.

b. Endovascular Implantation of Branching or Fenestrated Grafts in Aorta

The fenestrated (with holes) graft device is designed to treat patients with abdominal aortic aneurysms (AAA). Current treatment options for patients with AAAs include open surgical repair, endovascular repair using stent-grafts, or medical management.

Aneurysmal disease that extends proximally to the level of the renal arteries is usually indicative of more extensive aortic disease and comorbidities. As a result, many of these patients are at a higher overall risk when undergoing open surgical repair. In addition, these patients are often not suitable for endovascular treatment with currently available endografts because the length of healthy aorta is insufficient to provide an adequate seal at the proximal end. The indications for use for many of the standard endografts call for an aortic neck length greater than or equal to 15 millimeters.

Published industry reports estimate that 8 percent to 30 percent of patients with AAAs that need repair have aortic necks of less than 15 millimeters in length. One institution has reported that over half of its patients with AAAs were considered ineligible for endovascular aneurysm repair or endovascular aortic repair (EVAR) due to an inadequate length of nondiseased aorta. These patients also were predominantly contraindicated for open repair.

Prior to the development of a fenestrated graft device, the only treatment option available to a large number of these high-risk patients would have been medical management. Open surgical repair is too challenging to frail patients, as it requires supraceliac clamping of the aorta and may result in renal ischemia, mesenteric ischemia, or atheroembolization of the visceral vessels of the aorta. EVAR with a standard endograft is not a viable option either because the shortened neck precludes an adequate proximal end seal, which can lead to type I endoleaks (leaking of blood around the device into the aneurysm resulting in continued pressurization of the aneurysm). Medical management alone leaves these patients at high risk for AAA-related morbidity and mortality. These suboptimal choices led to the creation of fenestrated endografts that can seal above the renal arteries while maintaining access and uninterrupted blood flow to branch vessels of the aorta.

The fenestrated graft is currently under clinical trial in the United States, but has not yet received FDA approval. One of the two companies that are conducting clinical trials expects to receive FDA approval in the second quarter of 2012. Both companies listed on the FDA clinical trial Web site are still recruiting participants.

At the September 15, 2010 meeting of the ICD–9–CM Coordination and Maintenance Committee, the topic of fenestrated graft was presented with a request for a unique procedure code. As a result of that meeting, and additional meetings with manufacturers throughout the year, procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) was created for use beginning October 1, 2011 (FY 2012). This code is assigned to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively).

We have received a request from a manufacturer to reassign procedure code 39.78 from MS–DRGs 252, 253, and 254 and to MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively). The requestor stated that the assignment to MS–DRGs 252, 253, and 254 violates both of CMS' stated principles regarding assigning new codes to MS–DRGs that reflect both clinical coherence and similar consumption of resources.

From the standpoint of clinical coherence, the requestor noted that, while procedures in MS–DRGs 252, 253, and 254 are vascular procedures, the procedures do not involve the aorta. The requestor further notes that AAA repairs, both open and endovascular, are assigned to MS–DRGs 237 and 238. From the standpoint of similar consumption of resources, the requestor included anticipated device costs of $17,424 to $21,824 for a fenestrated endovascular procedure. The requestor noted that these costs only represent the device and do not include any additional resources required during the hospitalization. The requestor believed that the device costs are more similar to devices used in MS–DRGs 237 and 238.

CMS' practice is to assign new codes to MS–DRGs where similar procedures are also located. In terms of clinical coherence, CMS assigned the new code to the vascular procedure MS–DRGs (252, 253, and 254) where other noncoronary endovascular procedures for blood vessel repair also are assigned. This decision was based on our practice

to group similar procedures together, in this case repairs to blood vessels, especially for new codes when CMS has no data history.

With regard to resource consumption, we point out that procedure code 39.78 was created for use effective with discharges on or after October 1, 2011. Our review of data in the MedPAR file shows no utilization of this code because it is too new. That is, we have no claims data that would either prove or disprove the requestor's supposition that procedure code 39.78 is not adequately paid under MS–DRGs 252, 253, and 254. As discussed elsewhere in this preamble, CMS is not a device classification system. Therefore, because there are very few companies currently marketing their fenestrated graft devices, we are concerned that these companies are able to set their own charges in the market.

In addition, the requestor opined that ''an argument could possibly be made that the increased device costs and longer procedural times for [procedure code] 39.78 suggest assignment into MS–DRG 237 alone would be appropriate,'' although the requestor further stated that, without a significant volume of actual claims data, it might be more reasonable [for CMS] to take a conservative approach and assign these procedures to either MS–DRG 237 or MS–DRG 238. We note that MS–DRGs 237 and 238 are paired MS–DRGs, with both MS–DRGs containing the same procedure codes, but which have been subdivided based on the formula for the presence or absence of comorbid or complicating conditions. It is not an inherent part of the GROUPER logic to assign a code to only one DRG in a set of paired or triplicate MS–DRGs.

We will continue to evaluate the clinical coherence and resource consumption costs that impact this code and the current MS–DRG assignment. We also note that the requestor has expressed its intent to apply for New Technology status, provided that its anticipated FDA approval is granted in time for this year's IPPS update.

Because there is no data history for procedure code 39.78 that would justify a reassignment based on either clinical coherence or resource consumption, we are not proposing to make a change to the MS–DRG assignment of procedure code 39.78 for FY 2013. We believe that procedure code 39.78 has been appropriately placed within the MS–DRG structure. We are inviting public comment on our proposal.

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders): Disorders of Porphyrin Metabolism

We received a request for the creation of a new MS–DRG to better identify cases where patients with disorders of porphyrin metabolism exist, to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient access to necessary treatments. Porphyria is defined as a group of rare disorders (''porphyrias'') that interfere with the production of hemoglobin that is needed for red blood cells. While some of these disorders are genetic (inborn) and others can be acquired, they all result in the abnormal accumulation of hemoglobin building blocks, called porphyrins, which can be deposited in the tissues where they particularly interfere with the functioning of the nervous system and the skin.

Treatment for patients suffering from disorders of porphyrin metabolism consists of an intravenous injection of Panhematin® (hemin for injection). This pharmaceutical agent became the first drug approved under the Orphan Drug Act for rare diseases in 1983. It is the only FDA-approved prescription treatment for acute intermittent porphyria.

ICD–9–CM diagnosis code 277.1 (Disorders of porphyrin metabolism) describes these cases, which are currently assigned to MS–DRG 642 (Inborn and Other Disorders of Metabolism). We analyzed data from the FY 2011 MedPAR file for cases assigned to this MS–DRG. As shown in the table below, we found a total of 1,447 cases in MS–DRG 642 with an average length of stay of 4.63 days and average costs of $7,400. We then analyzed the data for cases reporting diagnosis code 277.1 as the principal diagnosis in this same MS–DRG. We found a total of 330 cases, with an average length of stay of 6.12 days and average costs of $11,476.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 642—All cases	1,447	4.63	$7,400
MS–DRG 642—Cases with principal diagnosis code 277.1	330	6.12	11,476

While the average costs for the 330 cases reporting a principal diagnosis code of 277.1 were higher than all cases in MS–DRG 642 ($11,476 versus $7,400), the volume of affected cases is small, representative of approximately 20 percent of all of the cases in MS–DRG 642. Under our existing policy (76 FR 51487 and 51488), in deciding whether to make modifications to the MS–DRGs, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different from the remaining patients in the MS–DRG. We evaluate the utilization of resources related to patient care using average costs and length of stay and rely on the judgment of our medical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we selected for review and the reminder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that were extreme in terms of charges or length of stay. Further, we consider the number of patients who have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases. Therefore, we have determined that the findings do not support the creation of a new MS–DRG.

We acknowledge the importance of ensuring that patients diagnosed with a disorder of porphyrin metabolism have adequate access to care and receive the necessary treatment. Despite the fact that our data analysis did not demonstrate support for the creation of a new MS–DRG at this time, we also explored an alternative option. In reviewing the medical MS–DRGs in terms of resources and clinical coherence that are also located within MDC 10, we found three MS–DRGs that we believe are similar to MS–DRG 642. We analyzed data from the MedPAR file on cases in MS–DRGs 643, 644, and 645 (Endocrine Disorders with MCC, with CC, and without CC/MCC, respectively) to determine if the cases reporting a principal diagnosis code of 277.1 would be more appropriately reassigned from MS–DRG 642 to MS–DRGs 643, 644, and 645. Upon examination of the data,

we found that the average costs of these cases were $10,835, $6,816, and $4,762, respectively, as shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 643—Cases with principal diagnosis code 277.1	6,562	7.11	$10,835
MS–DRG 644—Cases with principal diagnosis code 277.1	12,769	4.89	6,816
MS–DRG 645—Cases with principal diagnosis code 277.1	5,979	3.40	4,762

Based on these findings, if we were to reassign cases where disorders of porphyrin metabolism (diagnosis code 277.1) were reported as the principal diagnosis with a secondary diagnosis designated as a CC (MS–DRG 644) or with a secondary diagnosis that was not a CC/MCC (MS–DRG 645), Medicare would pay significantly less for these cases than they are now paid under MS–DRG 642. Therefore, it would not be appropriate to reassign cases reporting a principal diagnosis code of 277.1 from MS–DRG 642 to MS–DRGs 643, 644, and 645. In addition, our clinical advisors did not support this reassignment. The MS–DRG classification system on which the IPPS is based comprises a system of averages. As such, it is understood that, in any particular MS–DRG, it is not unusual for a small number of cases to demonstrate higher than average costs, nor is it unusual for a small number of cases to demonstrate lower than average costs. Upon review of the MedPAR data and the alternative option discussed, our clinical advisors agree that the current MS–DRG assignment for diagnoses of disorders of porphyrin metabolism (diagnosis code 277.1) to MS–DRG 642 is most appropriate at this time.

As stated previously, we acknowledge and recognize the severity of symptoms that patients diagnosed with disorders of porphyrin metabolism may experience. We also are sensitive to concerns about access to care and treatment for these patients. We will continue to monitor this issue and determine how to better account for the variation in resource utilization within the IPPS for these cases.

In summary, we are not proposing to create a new MS–DRG or to reassign cases reporting a principal diagnosis code of 277.1 to MS–DRGs 643, 644, and 645 for FY 2013. We are inviting public comment on our proposal.

5. Proposed Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

We are proposing to make a change to the MCE edits which includes the creation of a new length of stay edit for continuous invasive mechanical ventilation for 96 consecutive hours or more.

It was brought to our attention that a number of hospitals reporting ICD–9–CM procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) may be inaccurately reporting this code. As the title of the procedure code implies, a patient must have received continuous mechanical ventilation for 96 hours or more in order for this code to be assigned. This equates to a patient being hospitalized for at least a 4-day length of stay and having received continuous invasive mechanical ventilation for a minimum of 4 days. Therefore, a patient with a length of stay less than 4 days who received continuous invasive mechanical ventilation should not have procedure code 96.72 reported on the claim.

The ICD–9–CM classification system contains three procedure codes that identify and describe continuous invasive mechanical ventilation: Procedure code 96.70 (Continuous invasive mechanical ventilation of unspecified duration); procedure code 96.71 (Continuous invasive mechanical ventilation for less than 96 consecutive hours); and procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more). To assist in the accurate assignment of these codes, guidance in the form of a ''Note'' is provided within the designated procedure section of ICD–9–CM. This ''Note'' describes the calculation of the number of hours during a hospitalization in which a patient receives continuous invasive mechanical ventilation. In addition, coding advice pertaining to appropriate code assignment for mechanical ventilation has been published in various editions of the American Hospital Association's (AHA's) *Coding Clinic for ICD–9–CM.*

We analyzed the FY 2011 MedPAR data to determine how many cases reported procedure code 96.72 with a length of stay less than 4 days. Specifically, we reviewed cases reporting procedure code 96.72 with a length of stay of 1 day, 2 days, or 3 days. We found a total of 595 cases meeting those criteria. The data analysis showed there were 89 cases reporting procedure code 96.72 with a length of stay of 1 day and average costs of $5,948, 134 cases reporting procedure code 96.72 with a length of stay of 2 days and average costs of $7,776, and 372 cases reporting procedure code 96.72 with a length of stay of 3 days and average costs of $11,613.

The data also demonstrate that the 595 cases found were distributed across a wide range of MS–DRGs, with the top two (in terms of volume) being MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours) and MS–DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation 96+ hours). We note that the two MS–DRGs with the highest volume of cases reporting procedure code 96.72 and having a length of stay less than 4 days are the two MS–DRGs that specifically reference ''96+ hours'' in their titles. More importantly, a large percentage of these cases reporting procedure code 96.72 in error are being grouped to the incorrect MS–DRGs, resulting in significant overpayments. For example, of the 89 cases reporting procedure code 96.72 with a length of stay of 1 day, 31 cases were grouped to MS–DRGs 207 and 870. Of the 134 cases reporting procedure code 96.72 with a length of stay of 2 days, 54 cases were grouped to MS–DRGs 207 and 870. Lastly, of the 372 cases reporting procedure code 96.72 with a length of stay of 3 days, 160 cases were grouped to MS–DRGs 207 and 870. Therefore, the data show that a total of 245 cases (41 percent) were grouped to MS–DRGs 207 and 870 in error, resulting in approximately $25,000 in increased payments for each case (or approximately $6 million in increased payments for all 245 cases). Based on the results of these figures for that portion of the total 595 cases found,

there is an even larger dollar amount that is being overpaid to hospitals. These overpayments justify the proposed corrective actions.

However, we also note that the presumed amount of overpayments for claims having a length of stay less than 4 days, as discussed above, is merely an estimate based on the data analysis that has been conducted at this time. We are aware that, for particular circumstances such as those patients who may require observation services, it is possible to have procedure code 96.72 reported on the claim with a length of stay less than 4 days. Although unlikely, a patient might be briefly ventilated in an extended outpatient stay following a toxic ingestion with loss of protective reflexes or following outpatient procedures with a prolonged effect of anesthesia. A subsequent conversion to an inpatient stay would cause the costs to be attributable to the stay, while the days themselves were not reported in the inpatient date span on the claim. Similar effects could occur following an observation stay for a patient on chronic home or skilled nursing facility ventilation. It is for this reason that we are proposing a new edit in which claims found to have procedure code 96.72 with a length of stay less than 4 days would be returned to the provider for validation and resubmission. Instructions in the form of a Change Request (CR) would be issued prior to the implementation date. We are inviting the public to comment on our proposal to create this edit, effective for FY 2013.

6. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 1 and 2 and surgical class B includes MS–DRGs 3, 4, and 5. Assume also that the average costs of MS–DRG 1 is higher than that of MS–DRG 3, but the average costs of MS–DRGs 4 and 5 are higher than the average costs of MS–DRG 2. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed below.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients in the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

We are proposing limited changes to the MS–DRG classifications for FY 2013, as discussed in sections II.G.1. and 4. of this preamble. In our review of these proposed changes, we did not identify any needed changes to the surgical hierarchy. Therefore, we are not proposing any changes to the surgical hierarchy for Pre-MDCs and MDCs for FY 2013.

7. Complications or Comorbidity (CC) Exclusions List

a. Background

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. We refer readers to section II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47121 through 47152).

b. Proposed CC Exclusions List for FY 2013

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and

(3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As we indicated above, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we have made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC.[13]

(1) No Revisions Based on Changes to the ICD–9–CM Diagnosis Codes for FY 2013

For FY 2013, we are not proposing to make any revisions to the CC Exclusions List. There were no changes made to the ICD–9–CM coding system, effective October 1, 2012, due to the partial code freeze. (We refer readers to section II.G.9. of the preamble of this proposed rule for a discussion of ICD–9–CM coding system.)

(2) Suggested Changes to the MS–DRG Severity Levels for Diagnosis Codes for FY 2013

(A) Protein-Calorie Malnutrition

We received a request that we consider changing the severity levels for the following protein-calorie malnutrition diagnosis codes:

- 263.0 (Malnutrition of moderate degree)
- 263.1 (Malnutrition of mild degree)
- 263.9 (Unspecified protein-calorie malnutrition)

It was suggested that we change the severity level for diagnosis codes 263.0 and 263.1 from a non-CC to a CC, while changing the severity level for diagnosis code 263.9 from a CC to a non-CC. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). We indicated that we considered this comment outside of the scope of the proposed rule, as we did not propose any severity level changes to these codes for FY 2012, and did not address it in the final rule. However, we are addressing this issue in this FY 2013 proposed rule.

For this proposed rule, we analyzed the claims data in the FY 2011 MedPAR file for diagnosis codes 263.0, 263.1, and 263.9. We used the same approach we used in initially creating the MS–DRGs and classifying secondary diagnosis codes as non-CCs, CCs, or MCCs. A detailed discussion of the process and criteria we used in this process is described in the FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161). We refer the readers to this discussion for complete information on our approach to developing the non-CC, CC, and MCC lists. Each diagnosis for which Medicare data were available was evaluated to determine its impact on resource use and to determine the most appropriate CC subclass (non-CC, CC, or MCC) assignment. In order to make this determination, the average cost for each subset of cases was compared to the expected cost for cases in that subset. The following format was used to evaluate each diagnosis:

Code	Diagnosis	Cnt1	C1	Cnt2	C2	Cnt3	C3

Count (Cnt) is the number of patients in each subset. C1, C2, and C3 are a measure of the impact on resource use of patients in each of the subsets. The C1, C2, and C3 values are a measure of the ratio of average costs for patients with these conditions to the expected average cost across all cases. The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC. A value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. For additional details on this analysis, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161).

The following chart shows the analysis for each of the protein-calorie malnutrition diagnosis codes:

[13] See the FY 1989 final rule (53 FR 38485, September 30, 1988), for the revision made for the discharges occurring in FY 1989; the FY 1990 final rule (54 FR 36552, September 1, 1989), for the FY 1990 revision; the FY 1991 final rule (55 FR 36126, September 4, 1990), for the FY 1991 revision; the FY 1992 final rule (56 FR 43209, August 30, 1991) for the FY 1992 revision; the FY 1993 final rule (57 FR 39753, September 1, 1992), for the FY 1993 revision; the FY 1994 final rule (58 FR 46278, September 1, 1993), for the FY 1994 revisions; the FY 1995 final rule (59 FR 45334, September 1, 1994), for the FY 1995 revisions; the FY 1996 final rule (60 FR 45782, September 1, 1995), for the FY 1996 revisions; the FY 1997 final rule (61 FR 46171, August 30, 1996), for the FY 1997 revisions; the FY 1998 final rule (62 FR 45966, August 29, 1997) for the FY 1998 revisions; the FY 1999 final rule (63 FR 40954, July 31, 1998), for the FY 1999 revisions; the FY 2001 final rule (65 FR 47064, August 1, 2000), for the FY 2001 revisions; the FY 2002 final rule (66 FR 39851, August 1, 2001), for the FY 2002 revisions; the FY 2003 final rule (67 FR 49998, August 1, 2002), for the FY 2003 revisions; the FY 2004 final rule (68 FR 45364, August 1, 2003), for the FY 2004 revisions; the FY 2005 final rule (69 FR 49848, August 11, 2004), for the FY 2005 revisions; the FY 2006 final rule (70 FR 47640, August 12, 2005), for the FY 2006 revisions; the FY 2007 final rule (71 FR 47870) for the FY 2007 revisions; the FY 2008 final rule (72 FR 47130) for the FY 2008 revisions, the FY 2009 final rule (73 FR 48510), the FY 2010 final rule (74 FR 43799); the FY 2011 final rule (75 FR 50114); and the FY 2012 final rule (76 FR 51542). In the FY 2000 final rule (64 FR 41490, July 30, 1999, we did not modify the CC Exclusions List because we did not make any changes to the ICD–9–CM codes for FY 2000.

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
263.0	Malnutrition of moderate degree	Non-CC	6,040	2.14	21,383	2.61	21,635	3.20
263.1	Malnutrition of mild degree	Non-CC	4,139	2.22	11,598	2.50	8,921	3.13
263.9	Unspecified protein-calorie malnutrition	CC	2,737	2.16	165,825	2.54	178,044	3.34

We ran the following data as described in FY 2008 IPPS final rule with comment period (72 FR 47158 through 47161). The C1 value reflects a patient with no other secondary diagnosis or with all other secondary diagnoses that are non-CCs. The C2 value reflects a patient with at least one other secondary diagnosis that is a CC but none that is a MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is a MCC.

The chart above shows that the C1 findings ranged from a low of 2.14 to a high of 2.22. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as a MCC. The C1 findings suggest that these codes are more like a CC than a non-CC. The C2 findings ranged from 2.50 to 2.61. A value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or non-CC. The C2 findings of 2.50 for diagnosis code 263.1 and 2.54 for diagnosis code 263.9 suggest these codes are more similar to a CC than a non-CC, while the finding of 2.61 for diagnosis code 263.0 is borderline more similar to a MCC than a CC or non-CC when there is at least one other secondary diagnosis code that is a CC but none that is an MCC.

CC conditions typically have a C1 value over 1.75, a C2 value under 2.5, and a C3 value under 3.2. MCC conditions typically have a C1 value over 2.4, a C2 value over 2.8, and a C3 value over 3.3. We concluded that diagnosis code 263.0 is more similar to a CC than an MCC.

Therefore, the C1 and C2 findings support changing diagnosis codes 263.0 and 263.1 from a non-CC to a CC and maintaining code 263.9 as a CC. Our clinical advisors reviewed this issue and are in support of these findings that these conditions are more appropriately classified as CCs. Based on the data and clinical analysis, we are proposing for FY 2013 to change diagnosis codes 263.0 and 263.1 from a non-CC to a CC. We are not proposing any change to the severity level for diagnosis code 263.9. We are inviting public comment on our proposals.

(B) Antineoplastic Chemotherapy Induced Anemia

We received a request from a commenter that the severity level for diagnosis code 285.3 (Antineoplastic chemotherapy induced anemia) be changed from a non-CC to a CC. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). In that rule, we indicated that we considered this comment outside of the scope of the proposed rule because we did not propose any severity level changes to diagnosis code 285.3 for FY 2012; therefore, we did not address the issue in the final rule. However, we are addressing this issue in this FY 2013 proposed rule. We examined claims data in the FY 2011 MedPAR file for diagnosis code 285.3 according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
285.3	Antineoplastic chemotherapy induced anemia.	Non-CC	1,937	1.36	11,858	2.21	6,036	3.11

As discussed above, a value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value of close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 finding for diagnosis code 285.3 of 1.36 supports the current severity level of a non-CC. The C2 finding of 2.21 for diagnosis code 285.3 suggests that this code is more similar to a CC than a non-CC but not as significant as an MCC when there is at least one other secondary diagnosis code that is a CC. CC conditions typically have a C1 value over 1.75, a C2 value under 2.5, and a C3 value under 3.2.

Therefore, the C1 and C2 findings do not support changing the severity level for diagnosis code 285.3 to a CC. In addition, our clinical advisors reviewed this issue and support the decision not to change the severity level for diagnosis code 285.3 because the anemia is inherent in the treatment of cancer and does not qualify as a CC. As a result of our data analysis as well as the advice of our clinical advisors, we are not proposing any change to the severity level for diagnosis code 285.3 for FY 2013. We are inviting public comment on our proposal.

(C) Cardiomyopathy and Congestive Heart Failure, Unspecified

We received a comment that recommended changes to the severity levels for the cardiomyopathy and congestive heart failure, unspecified codes. The commenter recommended that cardiomyopathy codes, which are currently classified as CCs, be changed to non-CCs and diagnosis code 428.0 (Congestive heart failure, unspecified) be changed from a non-CC to a CC. According to the commenter, these proposed changes would better represent the resources utilized in caring for this population and reduce the administrative burden in clarifying these diagnoses with providers. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). We indicated that we considered this comment outside of the scope of the proposed rule because we did not propose any severity level changes to these codes for FY 2012; therefore, we did not address it in the final rule. However, we are addressing this issue in this FY 2013 proposed rule.

The commenter did not provide a list of the cardiomyopathy codes. We identified the following codes for analysis of the claims data in the FY 2011 MedPAR file:

• 425.4 (Other primary cardiomyopathies)
• 425.5 (Alcoholic cardiomyopathy)
• 425.7 (Nutritional and metabolic cardiomyopathy)
• 425.8 (Cardiomyopathy in other diseases classified elsewhere)
• 425.9 (Secondary cardiomyopathy, unspecified)
• 428.0 (Congestive heart failure, unspecified)

We did not include diagnosis codes 425.11(Hypertrophic obstructive cardiomyopathy) and 425.18 (Other hypertrophic cardiomyopathy) for our analysis because these two codes were created in FY 2012 and the data are not yet available. We examined claims data according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis description	CC Level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
425.4	Other primary cardiomyopathies	CC	39,489	1.47	243,719	2.18	139,689	3.20
425.5	Alcoholic cardiomyopathy	CC	438	1.68	2,643	2.19	1,670	3.26
425.7	Nutritional and metabolic cardiomyopathy	CC	60	1.18	869	2.17	799	3.14
425.8	Cardiomyopathy in other diseases classified elsewhere.	CC	940	1.19	5,967	2.15	5,171	3.14
425.9	Secondary cardiomyopathy, unspecified	CC	356	1.56	2,078	2.07	1.372	3.22
428.0	Congestive heart failure, unspecified	Non-CC	304,963	1.40	634,241	2.16	748,649	3.06

The table above shows that the C1 findings for the cardiomyopathy codes ranged from a low of 1.18 to a high of 1.68. A value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value of close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. The C1 findings suggest that the majority of these cardiomyopathy codes are more similar to a non-CC than a CC. The C2 findings ranged from a low of 2.07 to a high of 2.19. These findings suggest that these cardiomyopathy codes are more similar to a CC.

The C1 finding for diagnosis code 428.0 of 1.40 suggests that the condition is more similar to a non-CC than a CC. The C2 finding for diagnosis code 428.0 of 2.16 suggests that the secondary diagnosis is more similar to a CC than a non-CC.

The data are mixed between the C1 and C2 findings for the cardiomyopathy codes and do not consistently support a change in the severity level. Our clinical advisors reviewed these issues and are not in support of proposing any changes to the severity levels for these codes. Our clinical advisors stated that the diagnosis of cardiomyopathy (diagnosis codes 425.4 through 425.9) is generally severe, with significant impact on the patient requiring additional monitoring resources and cognitive effort, and is appropriately classified as a CC.

The data are mixed between the C1 and C2 findings for the congestive heart failure, unspecified, diagnosis code 428.0. Our clinical advisors reviewed these issues and are not in support of proposing any changes to the severity level of code 428.0. They indicated that diagnosis code 428.0 is very nonspecific and does not identify the severity of the heart failure, and concluded that the current classification for code 428.0 as a non-CC is appropriate. As a result of our data analysis and clinical advisors' review of these issues, we are not proposing any changes to the severity level for the cardiomyopathy and congestive heart failure, unspecified codes for FY 2013. We are inviting public comment on our proposal.

(D) Chronic Total Occlusion of Artery of the Extremities

We received a request to change the severity level designation for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities) to a CC. Currently, the diagnosis code is classified as a non-CC. Chronic total occlusion of artery of the extremities forms when plaque accumulates in an artery over an extended period of time, resulting in total cessation of blood flow. We analyzed claims data in the FY 2011 MedPAR file for this diagnosis code according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
440.4	Chronic total occlusion of artery of the extremities.	Non-CC	8,439	1.38	8,057	2.70	5,366	3.23

The C1 finding of 1.38 for diagnosis code 440.4 supports the current designation of this diagnosis code as a non-CC. However, the C2 findings of 2.70 suggests that this code is similar to a CC or perhaps an MCC, as this value is near to 3.0, which suggests that this condition is similar to an MCC. However, we would expect a higher C1 value such as 2.4 for this condition to qualify as an MCC.

The C1 and C2 findings support changing diagnosis code 440.4 from a non-CC to a CC. Our clinical advisors reviewed this issue and are in support of changing the severity level because this condition behaves as a CC. Therefore, we are proposing to change the severity level for diagnosis code 440.4 from a non-CC to a CC for FY 2013. We are inviting public comment on our proposal.

(E) Acute Kidney Failure With Other Specific Pathological Lesion in Kidney

We received a request to consider changing the severity level for diagnosis code 584.8 (Acute kidney failure with other specified pathological lesion in kidney). This diagnosis code's severity level is currently classified as an MCC. We examined claims data for this code in the FY 2011 MedPAR file according to the approach described above. The following table illustrates those findings.

Code	Diagnosis description	Severity level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
584.8	Acute kidney failure with other specified pathological lesion in kidney.	MCC	12	0.98	13	1.89	1,350	3.17

As discussed above, a C1 value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a diagnosis code that has been classified as a non-CC. A value close to 2.0 in the C1 field suggests that the condition is more similar to a CC severity level than a non-CC severity level, but not as significant in resource usage as an MCC severity level. In this case, the C1 value finding for diagnosis code 584.8 of 0.98 suggests that this diagnosis code is more similar to a non-CC than an MCC. A C2 value close to 3.0 suggests that the condition is more similar to an MCC than a CC or a non-CC. A C2 value close to 2.0 suggests that the condition is more similar to a CC than a non-CC. The C2 value finding for diagnosis code 584.8 of 1.89 supports classifying the severity level of this diagnosis code as a CC. Therefore, the C1 and C2 value findings support changing the severity level of diagnosis code 584.8 from an MCC to a lower severity level, that is, a CC. Our clinical advisors reviewed this issue and stated that this condition behaves as a CC. Therefore, they supported changing the severity level of this diagnosis code to a CC. Based on the clinical analysis and consistent with supporting claims data, we believe that the severity level of diagnosis code 584.8 should be changed from an MCC to a CC. Therefore, we are proposing to change the severity level of diagnosis code 584.8 from an MCC to a CC for FY 2013. We are inviting public comment on our proposal.

(F) Pressure Ulcer, Unstageable

We received a request to consider changing the severity level for diagnosis code 707.25 (Pressure ulcer, unstageable) from its current classification as a non-CC to an MCC. This issue was referred to as an out-of-scope public comment in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), but was not addressed in that rule.

For this FY 2013 proposed rule, we analyzed claims data for diagnosis code 707.25 from the FY 2011 MedPAR file according to the process and approach described above. The following table illustrates our findings:

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
707.25	Pressure ulcer, unstageable	Non-CC	1,839	1.87	7,161	2.46	13,285	3.08

As discussed above, a C1 value close to 2.0 suggests the condition is more similar to a CC than a non-CC severity level but not as significant in resource usage as an MCC. The C1 value finding of 1.87 for diagnosis code 707.25, which is near but not that close to a 2.0, suggests that this code is more similar to a CC than an MCC. A C2 value of close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C2 value finding for diagnosis code 707.25 is 2.46, which is not close to 3.0 and, therefore, the data do not support classifying this as an MCC. The C1 and C2 findings are more supportive of a classification as a CC than an MCC. There is another problem with this request to change diagnosis code 707.25 from a non-CC to an MCC. Currently, only stages III and IV pressure ulcers are MCCs. This unstageable code captures a pressure ulcer whose stage has not been determined. It would be inappropriate to assume that a pressure ulcer reported with diagnosis code 707.25 might be a stage III or IV pressure ulcer. Our claims data C1 and C2 findings do not support the fact that this code acts as an MCC. As mentioned earlier, the claims data are more supportive of a classification as a CC than an MCC. We asked our clinical advisors to review this issue. Our clinical advisors agree that the data findings and their own clinical evaluation support not changing the severity level of this diagnosis code to a CC or an MCC. Our clinical advisors recommend that unstageable pressure ulcers should continue to be classified as a non-CC because the stage is not clearly designated as a stage III or IV. Unstageable codes do not delineate what the stage of the ulcer might be. As a result of our data analysis as well as the advice of our clinical advisors, we believe that unstageable pressure ulcers should continue to be classified as a non-CC. Therefore, we are proposing that diagnosis code 707.25 remain a non-CC for FY 2013.

We are inviting public comment on our proposal not to change the severity level for diagnosis code 707.25 for FY 2013.

For FY 2013, there are proposed changes to Table 6G (Additions to the CC Exclusion List). As we discuss earlier, we are proposing to change the severity level for diagnosis codes 263.0, 263.1, and 440.4 from a non-CC to a CC. There are no proposed changes to Table 6H (Deletions to the CC Exclusion List). These tables, which contain codes that are effective for discharges occurring on or after October 1, 2012, are not being published in the Addendum to this proposed rule because of the length of the two tables. Instead, we are making them available through the Internet on the CMS Web site at: *http://www/cms.hhs.gov/AcuteInpatientPPS*. Each of these principal diagnosis for which there is a CC exclusion is shown in Tables 6G and 6H with an asterisk, and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis.

A complete updated MCC, CC, and Non-CC Exclusions List is available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS*. Beginning with discharges on or after October 1, 2011, the indented diagnoses were not recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

To assist readers in identifying the proposed changes to the MCC and CC lists that occur as a result of our review of severity levels for several ICD–9–CM diagnosis codes, we are providing the following summaries of those proposed MCC and CC changes for FY 2013. There will be no new, revised, or deleted diagnosis codes for FY 2013. Therefore, there will be no Tables 6A, 6C, and 6E published for FY 2013.

Summary of Proposed Additions to The MS–DRG MCC List—Table 6I.1

There are no proposed additions to the MS–DRG MCC List.

SUMMARY OF PROPOSED DELETIONS FROM THE MS–DRG MCC LIST—TABLE 6I.2

Code	Description
584.8	Acute kidney failure with other specified pathological lesion in kidney.

SUMMARY OF PROPOSED ADDITIONS TO THE MS–DRG CC LIST—TABLE 6J.1

Code	Description
263.0	Malnutrition of moderate degree.
263.1	Malnutrition of mild degree.
440.4	Chronic total occlusion of artery of the extremities.
584.8	Acute kidney failure with other specified pathological lesion in kidney.

Summary of Proposed Deletions From the MS–DRG CC List—Table 6J.2

There are no proposed deletions from the MS–DRG CC list.

Alternatively, the complete documentation of the GROUPER logic, including the current CC Exclusions List, is available from 3M/Health Information Systems (HIS), which, under contract with CMS, is responsible for updating and maintaining the GROUPER program. The current MS–DRG Definitions Manual, Version 29.0, is available on a CD for $225.00. Version 30.0 of this manual, which will include the final FY 2013 MS–DRG changes, will be available on a CD for $225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949–0303, or by obtaining an order form at the Web site: *http://www.3MHIS.com*. Please specify the revision or revisions requested.

8. Review of Procedure Codes in MS DRGs 981 Through 983; 984 Through 986; and 987 Through 989

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS–DRGs that we adopted for FY 2008, CMS DRG 468 was split three ways and became MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

MS–DRGs 981 through 983, 984 through 986, and 987 through 989 (formerly CMS DRGs 468, 476, and 477, respectively) are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. MS–DRGs 984 through 986 (previously CMS DRG 476) are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0, Incision of prostate
- 60.12, Open biopsy of prostate
- 60.15, Biopsy of periprostatic tissue
- 60.18, Other diagnostic procedures on prostate and periprostatic tissue
- 60.21, Transurethral prostatectomy
- 60.29, Other transurethral prostatectomy
- 60.61, Local excision of lesion of prostate
- 60.69, Prostatectomy, not elsewhere classified
- 60.81, Incision of periprostatic tissue
- 60.82, Excision of periprostatic tissue
- 60.93, Repair of prostate
- 60.94, Control of (postoperative) hemorrhage of prostate
- 60.95, Transurethral balloon dilation of the prostatic urethra
- 60.96, Transurethral destruction of prostate tissue by microwave thermotherapy
- 60.97, Other transurethral destruction of prostate tissue by other thermotherapy
- 60.99, Other operations on prostate

All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.[14]

Our review of MedPAR claims data showed that there were no cases that merited movement or should logically be assigned to any of the other MDCs.

[14] The original list of the ICD–9–CM procedure codes for the procedures we consider nonextensive procedures, if performed with an unrelated principal diagnosis, was published in Table 6C in section IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56 FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY 1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173), and the FY 1998 final rule (62 FR 45981), we moved several other procedures from DRG 468 to DRG 477, and some procedures from DRG 477 to DRG 468. No procedures were moved in FY 1999, as noted in the final rule (63 FR 40962); in FY 2000 (64 FR 41496); in FY 2001 (65 FR 47064); or in FY 2002 (66 FR 39852). In the FY 2003 final rule (67 FR 49999) we did not move any procedures from DRG 477. However, we did move procedure codes from DRG 468 and placed them in more clinically coherent DRGs. In the FY 2004 final rule (68 FR 45365), we moved several procedures from DRG 468 to DRGs 476 and 477 because the procedures are nonextensive. In the FY 2005 final rule (69 FR 48950), we moved one procedure from DRG 468 to 477. In addition, we added several existing procedures to DRGs 476 and 477. In the FY 2006 (70 FR 47317), we moved one procedure from DRG 468 and assigned it to DRG 477. In FY 2007, we moved one procedure from DRG 468 and assigned it to DRGs 479, 553, and 554. In FYs 2008, 2009, FY 2010, FY 2011 and FY 2012, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), the FY 2009 final rule (73 FR 48513), the FY 2010 final rule (74 FR 43796); the FY 2011 final rule (75 FR 50122); and the FY 2012 final rule (76 FR 51549).

Therefore, for FY 2013, we are not proposing to change the procedures assigned among these MS–DRGs.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. As noted above, there were no cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2013, we are not proposing to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

We also annually review the list of ICD–9–CM procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986 (Prostatic O.R. procedure unrelated to principal diagnosis with MCC, with CC, or without CC/MCC, respectively), and 987 through 989, to ascertain whether any of those procedures should be reassigned from one of these three MS–DRGs to another of the three MS–DRGs based on average charges and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

There were no cases representing shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2013, we are not proposing to move any procedure codes among these MS–DRGs.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs as described above in sections III.G.1. through 4. of this preamble, we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2013.

9. Proposed Changes to the ICD–9–CM Coding System, Including Discussion of the Replacement of the ICD–9–CM Coding System With the ICD–10–CM and ICD–10–PCS Systems in FY 2014

a. ICD–9–CM Coding System

The ICD–9–CM is a coding system currently used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD–9–CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Official Version of the ICD–9–CM contains the list of valid diagnosis and procedure codes. (The Official Version of the ICD–9–CM is available from the Government Printing Office on CD–ROM for $29.00 by calling (202) 512–1800.) Complete information on ordering the CD–ROM is also available at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/05_CDROM.asp#TopOfPage*. The Official Version of the ICD–9–CM is no longer available in printed manual form from the Federal Government; it is only available on CD–ROM. Users who need a paper version are referred to one of the many products available from publishing houses.

The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the *Tabular List* and *Alphabetic Index for Diseases,* while CMS has lead responsibility for the ICD–9–CM procedure codes included in the *Tabular List* and *Alphabetic Index for Procedures.*

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2013 at a public meeting held on September 14, 2011 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 18, 2011. For FY 2013, there were no changes to the ICD–9–CM coding system due to the partial code freeze or for new technology. Therefore, there will be no new, revised, or deleted diagnosis and procedure codes that are usually announced in Tables 6A (New Diagnosis Codes), 6B (New Procedure Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). Therefore, these tables will not be published as part of this FY 2013 proposed rulemaking.

Copies of the minutes of the procedure codes discussions at the Committee's September 14, 2011 meeting and March 5, 2012 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp*. The minutes of the diagnosis codes discussions at the September 14, 2011 meeting and March 5, 2012 meeting are found at: *http://www.cdc.gov/nchs/icd.htm*. These Web

sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–9–CM Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by E-mail to: *dfp4@cdc.gov*.

Questions and comments concerning the procedure codes should be addressed to: Patricia E. Brooks, Co-Chairperson, ICD–9–CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by E-mail to: *patricia.brooks2@cms.hhs.gov*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating ICD–9–CM codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the ''Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) * * * until the fiscal year that begins after such date.'' This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–9–CM Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the ICD–9–CM Coordination and Maintenance Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. The public decides whether or not to attend the meeting based on the topics listed on the agenda. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all changes to ICD–9–CM, both tabular and index, is published on the CMS and NCHS Web sites in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–9–CM Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April l, 2012 implementation of an ICD–9–CM code at the September 14, 2011 Committee meeting. Therefore, there were no new ICD–9–CM codes implemented on April 1, 2012.

Current addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/icd9ProviderDiagnosticCodes/01_overview.asp#TopofPage*. Information on ICD–9–CM diagnosis codes, along with the Official ICD–9–CM Coding Guidelines, can be found on the Web site at: *http://www.cdc.gov/nchs/icd9.htm*. Information on new, revised, and deleted ICD–9–CM codes is also provided to the AHA for publication in the *Coding Clinic for ICD–9–CM*. AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–9–CM coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

These same means of disseminating information on new, revised, and deleted ICD–9–CM codes will be used to notify providers, publishers, software vendors, contractors, and others of any changes to the ICD–9–CM codes that are implemented in April. The code titles are adopted as part of the ICD–9–CM Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to publish the October code updates in this manner within the IPPS proposed and final rules. For codes that are implemented in April, we will assign the new procedure code to the same MS–DRG in which its predecessor code was assigned so there will be no MS–DRG impact as far as

MS–DRG assignment. Any midyear coding updates will be available through the Web sites indicated above and through the *Coding Clinic for ICD–9–CM.* Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software systems. We will strive to have the April 1 updates available through these Web sites 5 months prior to implementation (that is, early November of the previous year), as is the case for the October 1 updates.

b. Code Freeze

The International Classification of Diseases, 10th Revision (ICD–10) coding system applicable to hospital inpatient services was to be implemented on October 1, 2013, as described in the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification: Modifications to Medical Data code Set Standards to Adopt ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362, January 16, 2009). However, the Secretary of Health and Human Services has issued a proposed rule that would delay, from October 1, 2013, to October 1, 2014, the compliance date for the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD–10). The proposed rule, CMS–0040–P, went on display at the Office of the Federal Register on April 9, 2012, and was published in the Federal Register on April 17, 2012 (77 FR 22950) and is available for viewing at: *http://www/gpo.gov/fdsys/browse/collection.action?collectionCode=FR*.

The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICM–10–PCS Guidelines for Coding and Reporting. In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD–9–CM and ICD–10–CM and ICD–10–PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease l year prior to the implementation of ICD–10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

We responded to comments in the ICD–10 final rule that the ICD–9–CM Coordination and Maintenance Committee has jurisdiction over any action impacting the ICD–9–CM and ICD–10 code sets. Therefore, we indicated that the issue of consideration of a moratorium on updates to the ICD–9–CM, ICD–10–CM, and ICD–10–PCS code sets in anticipation of the adoption of ICD–10–CM and ICD–10–PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. There was an announcement at the September 15–16, 2010 and September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meetings that a partial freeze of both ICD–9–CM and ICD–10 codes will be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets was made on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- On October 1, 2013, there were to be only limited code updates to ICD–10 code sets to capture new technology and diagnoses as required by section 503(a) of Pub. L. 108–173. There were to be no updates to ICD–9–CM on October 1, 2013, as the system would no longer be a HIPAA standard and, therefore, no longer be used for reporting. With the proposed ICD–10 implementation delay, there will be only limited code updates to both ICD–9–CM and ICD–10 to capture new technology and new diagnoses on October 1, 2013.
- On October 1, 2014, regular updates to ICD–10 were to begin. As stated earlier, HHS has issued a proposed rule that would delay the compliance date of ICD–10 from October 1, 2013, to October 1, 2014. If this delay is implemented, there would be only limited ICD–10 code updates for new technologies and new diseases on October 1, 2014. There will be no updates to ICD–9–CM on October 1, 2014, as the system will no longer be a HIPAA standard and, therefore, no longer be used for reporting. Full ICD–10 updates would begin on October 1, 2015, 1 year after the implementation of ICD–10.

The ICD–9–CM Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public will be encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 on or after October 1, 2014, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD–9–CM Coordination and Maintenance Committee Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03*. A summary of the September 14, 2011 Committee meeting, along with both written and audio transcripts of this meeting, are posted on the ''Download'' section of this Web page.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims

CMS is currently processing all 25 diagnosis codes and 25 procedure codes submitted on electronic hospital inpatient claims. Prior to January 1, 2011, hospitals could submit up to 25 diagnosis and 25 procedures; however, CMS' system limitations allowed for the processing of only the first 9 diagnosis codes and 6 procedure codes. We discussed this change in processing claims in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25843), in a correction notice issued in the **Federal Register** on June 14, 2011 (76 FR 24633), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51553). As discussed in these prior rules, CMS undertook an expansion of our internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update. We recognize the value of the additional information provided by this coded data for multiple uses such as for payment, quality measures, outcome analysis, and other important uses. We will continue to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format.

d. ICD–10 MS–DRGs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received comments on the creation of the ICD–10 version of the MS–DRGs, which will be implemented at the same time as ICD–10 (75 FR 50127 and 50128). As we

stated earlier, the Secretary of Health and Human Services has issued a proposed rule that would delay the compliance date of ICD–10 from October 1, 2013 to October 1, 2014. While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting our current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–9–CM Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to go about their own conversion projects. We posted ICD–10 MS–DRGs based on Version 26.0 (FY 2009) of the MS–DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for others to follow. All of this information can be found on the CMS Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. We have continued to keep the public updated on our maintenance efforts for ICD–10–CM and ICD–10–PCS coding systems as well as the General Equivalence Mappings that assist in conversion through the ICD–9–CM Coordination and Maintenance Committee. Information on these committee meetings can be found at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp*.

During FY 2011, we developed and posted Version 28.0 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRGs Version 28.0 also included the CC Exclusion List and the ICD–10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26.0. We also discussed this update at the September 15–16, 2010 and the March 9–10, 2011 meetings of the ICD–9–CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp*.

We reviewed comments on the ICD–10 MS–DRGs Version 28.0 and made updates as a result of these comments. We called the updated version the ICD–10 MS–DRGs Version 28 R1. We posted a Definitions Manual of ICD–10 MS–DRGs Version 28 R1 on our ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. To make the review of Version 28 R1 updates easier for the public, we also made available pilot software on a CD–ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD–10 MS–DRG Web page. We stated that we believed that, by providing the ICD–10 MS–DRG Version 28 R1 Pilot Software (distributed on CD–ROM), the public would be able to more easily review and provide feedback on updates to the ICD–10 MS–DRGs. We discussed the updated ICD–10 MS–DRGs Version 28 R1 at the September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD–10 MS–DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD–10 MS–DRGs Version 29.0, based on the FY 2012 MS–DRGs (Version 29.0) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD–10 MS–DRGs Version 29.0 on our ICD–10 MS–DRGs Web site. We also prepared a document that describes changes made from Version 28.0 to Version 29.0 to facilitate a review. The ICD–10 MS–DRGs Version 29.0 was discussed at the ICD–9–CM Coordination and Maintenance Committee meeting on March 5, 2012. Information was provided on the types of updates made. Once again the public was encouraged to review and comment on the most recent update to the ICD–10 MS–DRGs.

We provided information on a study conducted on the impact on converting MS–DRGs to ICD–10–CM and ICD–10–PCS. Information on this study is summarized in a paper entitled ''Impact of the Transition to ICD–10 on Medicare Inpatient Hospital Payments.'' This paper is posted on the CMS ICD–10 MS–DRG conversion Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. The paper describes CMS' approach to the conversion of the MS–DRGs from ICD–9–CM codes to ICD–10 codes. The study was undertaken using the ICD–9–CM MS–DRGs Version 27.0 (FY 2010) and converted to the ICD–10 MS–DRGs Version 27.0. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The paper was distributed and discussed at the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee. The impact of the conversion from ICD–9–CM to ICD–10 on Medicare MS–DRG hospital payments was estimated using 2009 Medicare data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.0. For detailed information on this study, we refer readers to the complete report which is posted on the CMS Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD–9–CM Coordination and Maintenance Committee meeting. This presentation followed presentations on the creation of ICD–10 MS–DRGs Version 29.0. A summary report of this meeting can be found on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp*. At this March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD–10 MS–DRGs. This update will provide additional information to the public as CMS is evaluating refinements made to the ICD–10 MS–DRGs based on public comments.

We will continue to work with the public to explain how we are approaching the conversion of MS–DRGs to ICD–10 and will post drafts of updates as they are developed for public review. The final version of the ICD–10 MS–DRGs will be implemented at the same time as ICD–10 and will be subject to notice and comment rulemaking. In the meantime, we will provide extensive and detailed information on this activity through the ICD–9–CM Coordination and Maintenance Committee.

H. Recalibration of MS–DRG Weights

1. Data Sources for Developing the Proposed Weights

In developing the proposed FY 2013 system of weights, we used two data sources: claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2011 MedPAR data used in this proposed rule include discharges occurring on October 1, 2010, through September 30, 2011, based on bills received by CMS through December 31, 2011, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2011 MedPAR file used in calculating the proposed relative weights includes data for approximately 10,354,422 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare

Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2011 update of the FY 2011 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2013 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year (that is, for the calculation of the FY 2013 MS–DRG relative weights, we use data from the FY 2010 HCRIS, which are data from cost reports that began on or after October 1, 2009 and before October 1, 2010). However, during the development of this proposed rule, we have found that those cost reports in the FY 2010 HCRIS dataset with fiscal year begin dates that are on or after May 1, 2010, and before October 1, 2010, are not accessible. This inaccessibility is because cost reports with fiscal year begin dates of May 1, 2010, through September 30, 2010, were filed on the new cost report Form 2552–10, and cost reports filed on Form 2552–10 are not currently accessible in the HCRIS. However, because data from cost reports filed on Form 2552–10 are not currently available, to ensure that the FY 2013 MS–DRG relative weights are calculated with a dataset that is as comprehensive and accurate as possible, we are proposing to calculate the FY 2013 MS–DRG relative weights with data from FY 2010 cost reports for providers with fiscal year begin dates of on or after October 1, 2009 and before May 1, 2010, and to backfill with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. We used cost report data for the December 31, 2011 update of the HCRIS for FY 2009 and FY 2010 in calculating the proposed FY 2013 relative cost-based weights.

2. Methodology for Calculation of the Proposed Relative Weights

The methodology we used to calculate the proposed FY 2013 MS–DRG cost-based relative weights based on claims data in the FY 2011 MedPAR file and data from the FY 2009 and FY 2010 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2013 MS–DRG classifications discussed in sections II.B. and G. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2010 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $10.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, special equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood charges, and anesthesia charges were also deleted.
- At least 96.3 percent of the providers in the MedPAR file had charges for 10 of the 15 cost centers. Claims for providers that did not have charges greater than zero for at least 10 of the 15 cost centers were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Thus, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all

claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 15 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 15 cost groups so that each MS–DRG had 15 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2009 and FY 2010 cost report data.

The 15 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 15 national cost center CCRs.

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Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_25	C_1_C6_25	D4_HOS_C2_25	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X-019X								
	Ward Charges	015X								
Intensive Days	Intensive Care Charges	020X		Intensive Care Unit	C_1_C5_26	C_1_C6_26	D4_HOS_C2_26	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_27	C_1_C6_27	D4_HOS_C2_27	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Burn Intensive Care Unit	C_1_C5_28	C_1_C6_28	D4_HOS_C2_28	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
				Surgical Intensive Care Unit	C_1_C5_29	C_1_C6_29	D4_HOS_C2_29	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
				Other Special Care Unit	C_1_C5_30	C_1_C6_30	D4_HOS_C2_30	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_48	C_1_C6_48	D4_HOS_C2_48	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64
						C_1_C7_48			C_1_C7_64	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Drugs Charged To Patient	C_1_C5_56	C_1_C6_56	D4_HOS_C2_56	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_56			C_1_C7_73	
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, and 0621, 0622, 0623		Medical Supplies Charged to Patients	C_1_C5_55	C_1_C6_55	D4_HOS_C2_55	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_55			C_1_C7_71	
		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_55.30	C_1_C6_55.30	D4_HOS_C2_55.30	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_55.30			C_1_C7_72	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299		DME-Rented	C_1_C5_66	C_1_C6_66	D4_HOS_C2_66	C_1_C5_96	C_1_C6_96	D3_HOS_C2_96
						C_1_C7_66			C_1_C7_96	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_67	C_1_C6_67	D4_HOS_C2_67	C_1_C5_77	C_1_C6_97	D3_HOS_C2_97
						C_1_C7_67			C_1_C7_97	
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_50	C_1_C6_50	D4_HOS_C2_50	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_50			C_1_C7_66	
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_51	C_1_C6_51	D4_HOS_C2_51	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_51			C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_52	C_1_C6_52	D4_HOS_C2_52	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68
						C_1_C7_52			C_1_C7_68	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_49	C_1_C6_49	D4_HOS_C2_49	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_49			C_1_C7_65	
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_37	C_1_C6_37	D4_HOS_C2_37	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
For all DRGs but Labor & Delivery						C_1_C7_37			C_1_C7_50	
		071X		Recovery Room	C_1_C5_38	C_1_C6_38	D4_HOS_C2_38	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51
						C_1_C7_38			C_1_C7_51	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_39	C_1_C6_39	D4_HOS_C2_39	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52
ONLY FOR THE 6 Labor & Delivery DRGs						C_1_C7_39			C_1_C7_52	
370, 371, 372, 373, 374, 375				Obstetrics Clinic	C_1_C5_63	C_1_C6_63	D4_HOS_C2_63	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_63			C_1_C7_93	
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_40	C_1_C6_40	D4_HOS_C2_40	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_40			C_1_C7_53	
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_53	C_1_C6_53	D4_HOS_C2_53	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_53			C_1_C7_69	
		0481		Cardiac Catheterization				C_1_C5_59	C_1_C6_59	D3_HOS_C2_59
									C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_44	C_1_C6_44	D4_HOS_C2_44	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60
						C_1_C7_44			C_1_C7_60	
				PBP Clinic Laboratory Services	C_1_C5_45	C_1_C6_45	D4_HOS_C2_45	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61
						C_1_C7_45			C_1_C7_61	
		074X, 086X		Electro-encephalography	C_1_C5_54	C_1_C6_54	D4_HOS_C2_54	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_54			C_1_C7_70	
Radiology	Radiology Charges	040X		Radiology - Diagnostic	C_1_C5_41	C_1_C6_41	D4_HOS_C2_41	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_41			C_1_C7_54	
		0333, 0339, 0342		Radiology - Therapeutic	C_1_C5_42	C_1_C6_42	D4_HOS_C2_42	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344		Radioisotope	C_1_C5_43	C_1_C6_43	D4_HOS_C2_43	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
						C_1_C7_43			C_1_C7_56	
		035X		Computed Tomography (CT) Scan				C_1_C5_57	C_1_C6_57	D3_HOS_C2_57
									C_1_C7_57	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	MRI Charges	061X		Magnetic Resonance Imaging (MRI)				C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
									C_1_C7_58	
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_61	C_1_C6_61	D4_HOS_C2_61	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91
						C_1_C7_61			C_1_C7_91	
Blood and Blood Products	Blood Charges	038x		Whole Blood & Packed Red Blood Cells	C_1_C5_46	C_1_C6_46	D4_HOS_C2_46	C_1_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_46			C_1_C7_62	
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_47	C_1_C6_47	D4_HOS_C2_47	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_47			C_1_C7_63	
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X,052X,053X								
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X								
				ASC (Non Distinct Part)	C_1_C5_58	C_1_C6_58	D4_HOS_C2_58	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
						C_1_C7_58			C_1_C7_75	
	Outpatient Service Charges	049X and 050X		Other Ancillary	C_1_C5_59	C_1_C6_59	D4_HOS_C2_59	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
	Lithotripsy Charge	079X				C_1_C7_59			C_1_C7_76	
	Clinic Visit Charges	051X		Clinic	C_1_C5_60	C_1_C6_60	D4_HOS_C2_60	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_60			C_1_C7_90	
	Ambulance Charges	054X		Ambulance	C_1_C5_65	C_1_C6_65	D4_HOS_C2_65	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_65			C_1_C7_95	
				Observation beds	C_1_C5_62	C_1_C6_62	D4_HOS_C2_62	C_1_C5_92	C_1_C6_92	D3_HOS_C2_92
						C_1_C7_62			C_1_C7_92	
					C_1_C5_6201	C_1_C6_6201	D4_HOS_C2_6201	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_6201			C_1_C7_92.01	
	ESRD Revenue Setting Charges	080X and 082X-088X (but not 086X)								
	(excluding Labor & Delivery DRGs)									

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Rural Health Clinic	C_1_C5_6350	C_1_C6_6350	D4_HOS_C2_6350	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88
	Professional Fees Charges	096X, 097X, and 098X				C_1_C7_6350			C_1_C7_88	
				FQHC	C_1_C5_6360	C_1_C6_6360	D4_HOS_C2_6360	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_6360			C_1_C7_89	
				Home Program Dialysis	C_1_C5_64	C_1_C6_64	D4_HOS_C2_64	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94
						C_1_C7_64			C_1_C7_94	
				Other Reimbursable	C_1_C5_68	C_1_C6_68	D4_HOS_C2_68	C_1_C5_98	C_1_C6_98	D3_HOS_C2_98
						C_1_C7_68			C_1_C7_68	

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3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2009 and FY 2010 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–4 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–4. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 15 cost centers by the corresponding national average CCR, we summed the 15 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The proposed FY 2013 cost-based relative weights were then normalized by an adjustment factor of 1.5877342556 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 15 proposed national average CCRs for FY 2013 are as follows:

Group	CCR
Routine Days	0.514
Intensive Days	0.442
Drugs	0.199
Supplies & Equipment	0.335
Therapy Services	0.370
Laboratory	0.142
Operating Room	0.238
Cardiology	0.145
Radiology	0.136
Emergency Room	0.226
Blood and Blood Products	0.389
Other Services	0.397
Labor & Delivery	0.451
Inhalation Therapy	0.189
Anesthesia	0.109

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. In this FY 2013 IPPS/LTCH PPS proposed rule, we are proposing to use that same case threshold in recalibrating the MS–DRG weights for FY 2013. Using data from the FY 2011 MedPAR file, there were 8 MS–DRGs that contain fewer than 10 cases. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients aged 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have received frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS–DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS–DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS–DRGs for newborns. All of the low-volume MS–DRGs listed below are for newborns. In FY 2013, because we do not have sufficient MedPAR data to set accurate and stable cost weights for these low-volume MS–DRGs, we are proposing to compute weights for the low-volume MS–DRGs by adjusting their FY 2012 weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown below:

Low-volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
768	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C.	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

4. Bundled Payments for Care Improvement (BPCI) Initiative

a. Background

Section 3021 of the Affordable Care Act, codified at section 1115A of the Act, authorizes CMS to test innovative payment and service delivery models with the goal of reducing Medicare program expenditures while preserving or enhancing the quality of care furnished to individuals. Because initiatives established under this authority could result in IPPS hospitals receiving a payment different than what they otherwise would receive under the IPPS, we believe it is important to identify how these initiatives are addressed in the context of MS–DRG recalibration and ratesetting, budget neutrality, and the impact analysis in the Addendum of this proposed rule.

Under the Bundled Payments for Care Improvement (BPCI) initiative, CMS would link payments for multiple services that patients receive during an episode of care. CMS is working in partnership with providers to develop and test models of bundling payments through the BPCI initiative. On August 23, 2011, CMS invited providers to apply to help develop and test four different models of bundling payments. For additional information, we refer readers to the CMS Web site at: *http://www.innovations.cms.gov/initiatives/Bundled-Payments/index.html*. We are providing below a brief overview of payments under each model. However, the BPCI initiative Request for Application and related information on the CMS Web site at *http://innovations.cms.gov/initiatives/bundled-payments/* provide more details of this initiative.

As described below and also in the Addendum to this proposed rule, we are generally proposing to include data from hospitals participating in the BPCI initiative and to treat these hospitals without regard to their participation in the BPCI initiative for the purposes of IPPS ratesetting.

Model 1

In Model 1, the episode of care is defined as the inpatient hospital services for the acute care hospital stay only. Applicants for this model were asked to propose discount percentages for various periods of the 3-year program, which would be applied to the IPPS operating MS–DRG payment for each participating hospital's MS–DRGs over the lifetime of the initiative. That is, for hospitals participating in Model 1, Medicare would continue to pay participating acute care hospitals under the IPPS. However, these payments to participating acute care hospitals would be at a reduced payment amount that reflects the applicable discount percentage for cases in all MS–DRGs for the specific period of the program. We note that an adjustment would be made such that payments for IME, DSH, and outliers would be calculated based on the nondiscounted MS–DRG operating IPPS payment amount and then paid, if applicable, in addition to the discounted MS–DRG operating IPPS payment. The minimum discount percentage that awardees are expected to offer would be phased in over time, with the discount percentage updated as frequently as every 6 months.

Model 2

In Model 2, the episode of care is defined as the inpatient acute care hospital stay for specific clinical conditions and a specified period of time following discharge (with a minimum episode length of at least 30 days following hospital discharge). The payment bundle for Model 2 would encompass all Medicare Part A payments for designated MS–DRGs, Part B professional services paid under the Medicare Physician Fee Schedule (MPFS) during the hospital stay, and related professional services furnished after discharge during the episode, ''related readmissions'' (as defined under the BPCI initiative), care by a postacute care provider such as an HHA, IRF, SNF, LTCH, and other related services furnished during the episode (that is, all Medicare Part A and Part B with the exception of hospice care). Applicants, which may be a Medicare supplier or provider, groups of such entities, or other organizations that bring together providers and suppliers to test the model, are asked to propose specific MS–DRG(s) for the clinical condition(s) to be tested in Model 2. Furthermore, the applicants are asked to propose the target price on an MS–DRG basis for the episode that includes a single rate of discount off of the expected Medicare payment (including hospital, postacute care, Medicare Part B professional services, and other services, as applicable) for all Model 2 beneficiaries discharged from the inpatient hospital stay with the specified MS–DRG(s). We note that, when proposing the target price, applicants are instructed to include IPPS outlier payments in their calculation; however, IPPS IME and DSH payments should be excluded from the target price. In Model 2, payments would be made at the usual fee-for-service payment rates to the participating providers through the regular claims processing system, after which the aggregate Medicare payment for the episode would be reconciled against the target price. If aggregate Medicare expenditures are less than the target price, the awardee would be paid the difference as a reconciliation payment. Conversely, if aggregate Medicare expenditures exceed the target price, CMS would recoup that amount from the awardee.

Model 3

In Model 3, the episode of care begins at initiation of postacute services at one of four postacute care providers (HHAs, IRFs, SNFs, and LTCHs) within 30 days after discharge from any acute care hospital for specific clinical conditions. As with the other three models, applicants may be one or more Medicare providers or supplier or other organization(s) bringing those entities together to test the model. Applicants are asked to propose an episode length that would extend to at least 30 days following initiation of care at an HHA, IRF, SNF, or LTCH. The payment bundle for Model 3 would encompass care by a postacute care provider, and other related services furnished during the episode, including Medicare Part B professional services paid under the MPFS, and inpatient hospital readmissions (as defined under the BPCI initiative). In contrast to Model 2, the payment bundle for Model 3 does not include services provided in the initial acute care hospital stay. We note that, while the episode is initiated at one of the four postacute care providers rather than at an acute care hospital, applicants are asked to specify the clinical condition(s) to be tested in Model 3 by proposing relevant MS–DRG(s). Therefore, applicable to all Model 3 beneficiaries discharged from any inpatient acute care hospital stay with the specified MS–DRG(s), applicants are to propose a target price on an MS–DRG basis for the episode that includes a single rate of discount off of the expected Medicare payment, which includes care by a postacute care provider, related Medicare Part B professional services paid under the MPFS, inpatient hospital readmissions, and other related services furnished during the episode. In Model 3, payments would be made at the usual fee-for-service payment rates to the participating providers through the regular claims processing process, after which the aggregate Medicare payment for the episode would be reconciled against the target price. Like Model 2, if aggregate Medicare expenditures are less than the target price, the awardee would be paid the difference as a reconciliation payment. Conversely, if

aggregate Medicare expenditures exceed the target price, CMS would recoup that amount from the awardee. We note that Model 3 does address payment for related hospital readmissions.

Model 4

In Model 4, the episode of care is defined as the acute care hospital stay and includes all ''related readmissions'' (as defined under the BPCI initiative). The payment bundle for Model 4 would encompass Medicare inpatient hospital services, Medicare Part B professional services paid under the MPFS furnished during the initial hospitalization, as well as hospital services and Medicare Part B professional services during any related readmissions. Applicants are asked to propose specific MS–DRG(s) for the clinical condition(s) to be tested in Model 4. Applicants for this model are asked to propose a target price for the episode that includes a single rate of discount off of expected Medicare payment (including both Medicare Part A hospital services and Part B professional services) for all beneficiaries discharged from the inpatient hospital stay with the specified MS–DRG(s).

In contrast to Models 2 and 3, where usual Medicare fee-for-service payments are made to all providers and reconciliation of Medicare spending against the target price for the episode is conducted retrospectively, under Model 4, hospitals would receive a prospectively established bundled payment for specified MS–DRGs. This payment would include both the MS–DRG payment for the hospital and a fixed payment amount for the Medicare Part B professional services anticipated to be furnished during the episode. That is, separate payment for providers' professional services furnished during the inpatient hospital stay would not be made. Participating Model 4 hospitals receiving payment would take responsibility for distributing payment to providers that would otherwise be paid separately. We note that IPPS IME and DSH payments to Model 4 hospitals would be calculated based on the nondiscounted base MS–DRG operating IPPS payment that would have been made in the absence of the model. Other applicable payment adjustors would also be calculated based on the base MS–DRG operating IPPS payment amount that would otherwise have applied to the case, as opposed to the prospectively established amount paid through this initiative, which would be higher as it includes payment for Part B services as well as the base MS–DRG payment. Under Model 4, no separate IPPS outlier payments would be made.

b. Proposed Treatment of Data From Hospitals Participating in the BPCI Initiative

As discussed above, acute care hospitals have the opportunity to apply and participate in the BPCI payment models described above. For Model 1 and Model 2, participating acute care hospitals would continue to receive an IPPS payment under section 1886(d) of the Act (subject to a predetermined discount for hospitals participating in Model 1). For Model 2, participating hospitals may also receive a reconciliation payment under the BPCI initiative (based on their predetermined target price). Under Model 3, services provided in the initial acute care hospital stay are not included; however, the model does address payment for possible hospital readmissions. Under Model 1, hospitals participate for all MS–DRGs, while, under Model 2, hospitals participate for only pre-selected MS–DRGs. We believe it is appropriate to include all applicable data from these subsection(d) hospitals in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act (in addition to, with respect to Model 2 hospitals, any reconciliation payment the hospital may receive under the BPCI initiative). Moreover, even if these hospitals were not receiving IPPS payments under section 1886(d) of the Act (and were participating in Models 1 and 2), the Secretary has the authority to make appropriate adjustments for payment amounts under section 1886(d)(5)(I)(i) of the Act to include all applicable data from these subsection(d) hospitals in our IPPS ratesetting calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS, short-term, acute care hospitals within the IPPS ratesetting calculations because excluding these hospitals would diminish the number of providers used to determine the IPPS rates, which could cause fluctuations in the IPPS rates and could produce instability to the IPPS rates. Therefore, because we believe it is appropriate to include all claims from hospitals participating within Models 1 and 2 within the IPPS ratesetting calculations, using the Secretary's authority under section 1886(d)(5)(I)(i) of the Act, we are proposing to include all applicable data from ''subsection (d)'' hospitals participating in Models 1 and 2 under the BPCI initiative in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS–DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis). In essence, we would continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these two bundled payment models (that is, we would treat these hospitals as if they are not participating in Model 1 or Model 2 under the BPCI initiative).

In contrast to BPCI Models 1 and 2 (wherein participating IPPS hospitals would receive an IPPS payment under section 1886(d) of the Act, and, in the case of Model 2, may also receive a reconciliation payment under the BPCI initiative), IPPS hospitals participating in Model 4 would receive a predetermined bundled payment for Medicare Part A and Part B services for a pre-specified MS–DRG ''episode'' (and any ''related readmissions'' as defined under the BPCI initiative). These bundled payments are for certain pre-specified MS- DRG(s) episodes (not all cases) and would be made in accordance with the terms of the model, as authorized by section 1115A of the Act (these IPPS hospitals would also receive ''regular'' IPPS payments under section 1886(d) of the Act for those MS–DRGs not included in the bundling model). Similar to Models 1 and 2, we believe it is appropriate to keep all applicable data from these ''subsection (d)'' hospitals in our IPPS payment modeling and ratesetting calculations because the majority of Medicare payments these hospitals would receive would be IPPS payments under section 1886(d) of the Act (that is, payments for cases in MS–DRGs that are not included in the bundled payment model). Moreover, although these hospitals are not receiving payments under 1886(d) of the Act for the cases included in the prospective bundled payment under Model 4, the Secretary has the authority to make appropriate adjustments for payment amounts at section 1886(d)(5)(I)(i) of the Act to include all applicable data from these subsection(d) hospitals in our IPPS ratesetting calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS, short-term, acute care hospitals and their claims within the IPPS ratesetting calculations because excluding these hospitals would diminish the number of providers used to determine the IPPS rates, which could cause fluctuations in the IPPS rates and could produce

instability to the IPPS rates. Therefore, because we believe it is appropriate to include all claims from hospitals participating within Models 1 and 2 within the IPPS ratesetting calculations and use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include those hospitals and claims, we also believe it is appropriate to include all applicable data from subsection (d) hospitals participating in Model 4 in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS–DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) and propose to do so. In essence, we would continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within this bundled payment model (that is, we would treat these hospitals as if they are not participating in Model 4 under the BPCI initiative).

We note that Model 3 only addresses payments for related readmissions and postacute care services (rather than IPPS payments). Therefore, we believe it is not necessary to propose to address the treatment of any data for participating hospitals in Model 3.

I. Proposed Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, ''based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.'' We note that beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs.

The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in 42 CFR 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In the FY 2006 IPPS final rule (70 FR 47351) and FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we explained our policy regarding substantial similarity in detail.

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to the discharge involving the new medical services or technologies must be assessed for adequacy. Under the cost criterion, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2012 IPPS/LTCH PPS final rule contains the final thresholds that will be used to evaluate applications for new technology add-on payments for FY 2013. We refer readers to the Web site *http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp#TopOfPage* for a complete viewing of Table 10 from the FY 2012 IPPS/LTCH PPS final rule.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR Parts 160 and 164 applies to claims information that providers submit with applications for new technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents ''an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.'' For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a complete discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on

payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criteria, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Office of Clinical Standards and Quality (OCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, OCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in August 2008 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf.*

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov.*

We note that applicants for add-on payments for new medical services or technologies for FY 2014 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2014, the Web site also will post the tracking forms completed by each applicant.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2013 prior to publication of this FY 2013 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 18, 2011 (76 FR 71571 through 71572), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 14, 2012. In the announcement notice for the meeting, we stated that the opinions and alternatives provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2013 new medical service and technology add-on payment applications before the publication of this FY 2013 proposed rule.

Approximately 70 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. Four of the five FY 2013

applicants presented information on its technology, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of March 6, 2012, in our evaluation of the new technology add-on applications for FY 2013 in this proposed rule.

In response to the published notice and the new technology town hall meeting, we received written comments regarding applications for FY 2013 new technology add-on payments. We summarize these comments below or, if applicable, indicate that there were no comments received, at the end of each discussion of the individual applications in this proposed rule.

Comment: A number of attendees at the new technology town hall meeting provided comments that were unrelated to the issue of whether the FY 2013 new technology add-on applications met the ''substantial clinical improvement'' criterion.

Response: As explained above and in the **Federal Register** notice announcing the new technology town hall meeting (76 FR 71571), the purpose of the new technology town hall meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology applications for FY 2013. Therefore, we are not summarizing those comments in this proposed rule. Commenters are welcome to resubmit these comments in response to proposals presented in this proposed rule.

3. FY 2013 Status of Technology Approved for FY 2012 Add-On Payments: Auto Laser Interstitial Thermal Therapy (AutoLITT™) System

Monteris Medical submitted an application for new technology add-on payments for FY 2011 for the AutoLITT™. AutoLITT™ is a minimally invasive, MRI-guided laser tipped catheter designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue. The technology can be identified by ICD–9–CM procedure codes 17.61 (Laser interstitial thermal therapy [LITT] of lesion or tissue of brain under guidance), and 17.62 (Laser interstitial thermal therapy [LITT] of lesion or tissue of head and neck under guidance), which became effective on October 1, 2009.

The AutoLITT™ received a 510K FDA clearance in May 2009. The AutoLITT™ is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. The AutoLITT™ may be used in patients with glioblastoma multiforme brain tumors. The applicant stated in its application and through supplemental information that, due to required updates, the technology was actually introduced to the market in December 2009. The applicant explained that it was necessary to reduce the thermal damage lines from three to one and complete International Electrotechnical Commission/Underwriter Laboratory testing, which led to the introduction of the technology to the market in December 2009, although the technology was approved by FDA in May 2009. The applicant also stated through supplementary information to its application that the first sale of the product took place on March 19, 2010. However, because the product was already available for use in December 2009, it appears that the newness date would begin in December 2009. In the FY 2011 IPPS/LTCH PPS proposed rule, we welcomed public comments on this issue.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the AutoLITT™ and consideration of the public comments we received in response to the FY 2011 IPPS/RY 2011 LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the AutoLITT™ for new technology add-on payments for FY 2011. Consistent with the applicant's clinical trial, the add-on payment is intended only for use of the device in cases of glioblastoma multiforme. Therefore, we limited the new technology add-on payment to cases involving the AutoLITT™ in MS–DRGs 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and 027 (Craniotomy and Endovascular Intracranial Procedures without CC or MCC). Cases involving the AutoLITT™ that are eligible for the new technology add-on payment are identified by assignment to MS–DRGs 025, 026, and 027 with a procedure code of 17.61 (Laser interstitial thermotherapy of lesion or tissue of brain under guidance) in combination with a principal diagnosis code that begins with a prefix of 191 (Malignant neoplasm of brain). We note that using the procedure and diagnosis codes above and restricting the add-on payment to cases that map to MS–DRGs 025, 026, and 027 is consistent with information provided by the applicant, which demonstrated that cases of the AutoLITT™ would only map to MS–DRGs 025, 026, and 027. Procedure code 17.62 (Laser interstitial thermotherapy of lesion or tissue of head and neck under guidance) does not map to MS–DRGs 025, 026, or 027 under the GROUPER software and, therefore, is ineligible for new technology add-on payment.

The average cost of the AutoLITT™ is reported as $10,600 per case. Under § 412.88(a)(2) of the regulations, new technology add-on payments are limited to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case involving the AutoLITT™ is $5,300.

The new technology add-on payment regulations provide that ''a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new medical service or technology'' (42 CFR 412.87(b)(2)). Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362). With regard to the newness criterion for the AutoLITT™, as stated above, we consider the beginning of the newness period for the device to commence from the market release date of December 2009. Therefore, for FY 2013, as of December 2012, the AutoLITT™ will have been on the market for 3 years, and would therefore no longer be considered ''new'' as of December 2012 nor be considered eligible for new technology add-on payments in FY 2013. However, we received information from the manufacturer that the market release date of the AutoLITT™ occurred after April 2010 (which occurs in the latter half of the fiscal year) and, therefore, it appears that the AutoLITT™ would still be considered ''new'' for FY 2013 and would still be eligible for new technology add-on payments in FY 2013. We note that we received this information in close proximity to the

publication of the proposed rule and anticipate receiving further information on the delayed market release date from the manufacturer and welcome public comment as well.

4. FY 2013 Applications for New Technology Add-On Payments

We received six applications for new technology add-on payments for FY 2013. However, two applicants withdrew their applications prior to the publication of this proposed rule.

a. Glucarpidase (Trade Brand Voraxaze®)

BTG International, Inc. submitted an application for new technology add-on payments for Glucarpidase (trade brand Voraxaze®) for FY 2013. Glucarpidase is used in the treatment of patients who have been diagnosed with toxic methotrexate (MTX) concentrations as a result of renal impairment. The administration of Glucarpidase causes a rapid and sustained reduction of toxic MTX concentrations.

Methotrexate (MTX) is a widely used anticancer agent. The administration of high-dose methotrexate (HDMTX) is an important component of the treatment provided to patients who have been diagnosed with various types of cancer. According to the applicant, HDMTX, in particular, is specifically used in the treatment of patients who have been diagnosed with osteosarcoma, acute lymphoblastic leukemia, non-Hodgkin's lymphoma, or primary CNS lymphoma. The applicant further stated that the administration of HDMTX can cause renal dysfunction. Renal dysfunction impairs the elimination of MTX, which in turn causes the levels of MTX to rise to the point of life-threatening toxicity.

The applicant maintains that there are not any currently FDA-approved pharmaceutical treatment options available to rapidly decrease MTX levels in patients who have been diagnosed with toxic MTX concentrations as a result of renal impairment. The applicant asserts that extracorporeal treatment options that are routinely employed to rapidly treat this condition, such as hemodialysis, hemodiafiltration, high-flux hemodialysis, charcoal hemoperfusion or hemofiltration, peritoneal dialysis, exchange transfusion, or plasma exchange, are invasive, may add excess morbidity to the treatment regimen, and have proven to have limited effects.[15] High flux hemodialysis is the most effective method of extracorporeal MTX removal, but this method requires 5 to 6 days of daily treatment (4 to 6 hours per session).[16] The risks associated with repeated hemodialysis procedures such as anemia, infection, and increased mortality, especially in neutropenic or thrombocytopenic patients, are significant and cause rebounds in MTX levels. The applicant maintains that other treatment options, such as the administration of leucovorin, hydration, and urinary alkalinization, also are commonly used to reduce harmful levels of MTX. However, these treatment options do not reduce toxic MTX concentrations in all patient populations.[17]

Voraxaze® is an orphan drug that was approved by the FDA on January 17, 2012. Beginning in 1993, certain patients could obtain expanded access for treatment use to Voraxaze® as an investigational drug. Since 2007, the applicant has been authorized to recover the costs of making Voraxaze® available through its expanded access program. We describe expanded access for treatment use of investigational drugs and authorization to recover certain costs of investigational drugs in more detail below. The applicant intends to make Voraxaze® available on the market in the United States as a commercial product to the larger population in April 2012.

With regard to newness, we are concerned that Voraxaze® may no longer be considered ''new''. Specifically, section 1886(d)(5)(K)(ii)(II) of the Act requires that we provide for the collection of cost data for a new medical service or technology for a period of at least 2 years and no more than 3 years ''beginning on the date on which an inpatient hospital code is issued with respect to the service or technology''. In addition, the regulations at § 412.87(b)(2) state that ''A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section.'' As we have indicated in the past, we generally believe that the newness period begins on the date that FDA approval is granted. The FDA approval date is typically the date when new technologies are available on the market and as a result begin to be reflected within the MS–DRGs cost data.

As noted above, Voraxaze® was approved by the FDA in January 2012. However, starting in 1993, certain patients were able to obtain access to Voraxaze® as an investigational drug through an expanded access program, and the applicant has been authorized to recover certain costs of making Voraxaze® available through its expanded access program since 2007. We discuss below in more detail whether the cost of Voraxaze® is already reflected within the MS–DRG relative weights.

To determine the date of newness for Voraxaze®, we believe it is appropriate to compare investigational drugs provided under the expanded access program to devices eligible for the Humanitarian Use Device (HUD) Program because these programs contain similarities to evaluate the newness criterion.

In prior final rules, we have evaluated and approved technologies with a Humanitarian Device Exemption (HDE) approval. In the FY 2010 IPPS/LTCH PPS final rule, we approved new technology add-on payments for the Spiration® IBV®, which received a HDE approval from the FDA on October 24, 2008, and had its first IRB approval on March 12, 2009 (74 FR 43754, 43819). Therefore, technologies with an HDE approval may be eligible for new technology add-on payments. In other words, we have concluded that HDE approval constitutes an FDA approval in the context of the newness criterion and would begin the newness period, subject to market availability.

There are separate processes and standards for providing expanded access to investigational drugs for treatment use and for the HUD Program. The term ''expanded access'' refers to the use of investigational drugs, or approved drugs where availability is limited by a risk evaluation or mitigation strategy, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. When the requirements in (FDA's regulations at) 21 CFR part 312, Subpart I are met, a patient or group of patients with a serious or immediately life-threatening disease or condition, and no comparable or satisfactory alternative therapy, may obtain expanded access to an investigational drug. When patients obtain expanded access to an unapproved investigational drug, the safety and effectiveness of the drug have

[15] Widemann *et al.,* [Cancer, 2004, and Vilay *et al.,*], Pharmacotherapy, Vol 30, January, 2010).

[16] Wall *et al.,* American Journal of Kidney Diseases, Vol. 28, No. 6, 1996.

[17] Pinedo *et al,* Cancer Research, 36, 4418–4424 December, 1976.

not been fully established, and the drug does not have formal FDA approval under a New Drug Application (NDA) or Biologics Licensing Application (BLA) for commercial marketing. Manufacturers may continue conducting clinical trials in parallel to the expanded access program in order to pursue formal market approval from the FDA under an NDA or BLA for commercial marketing. The FDA's Office of Orphan Products Development administers the HUD Program. A HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. To obtain approval for a HUD, a HDE application is submitted to FDA. A HDE application is similar in both form and content to a Premarket Approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. A HDE application must, however, contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. An approved HDE authorizes marketing of the HUD, however, an HDE approval requires that the device only be used in facilities that have established a local Institutional Review Board (IRB) to supervise clinical testing of devices, and that an IRB approve the use of the device to treat or diagnose the specific disease. Although HUDs can be marketed, they are subject to a general prohibition on profit; that is, they may not, except in narrow circumstances, be sold for an amount that exceeds the cost of research and development, fabrication and distribution.

Expanded access to investigational drugs and the HUD Program have similarities and differences that are relevant to the newness criterion. Both have limits on who is eligible to receive a drug or use a device. In addition, to satisfy the requirements for expanded access in FDA's regulations, and for a HDE to meet the standard for approval, a sponsor is not required to demonstrate effectiveness of the product at the same level as for approval of a PMA, NDA, or BLA. Expanded access to investigational drugs and the HUD Program differ in many ways, including that the HUD Program is for devices, and the expanded access programs provide access to drugs. In addition, under the HUD Program, the device is granted FDA approval for limited use. However, while FDA authorizes expanded access to an investigational drug, FDA does not approve the investigational drug when it authorizes expanded access.

This second difference is key to our interpretation of our policy to recognize a HDE approval as an FDA approval. We believe that the availability of a drug through the expanded access program would not constitute FDA approval in the context of the newness criterion because unapproved, investigational drugs made available to certain patients through the expanded access program do not receive FDA approval prior to enrollment in the program and cannot be marketed. In other words, we believe that for the purposes of evaluating whether a new technology meets the newness criterion, it may be appropriate not to consider the date when Voraxaze® became available to certain patients through the applicant's expanded access program as the date of market availability.

We note that cost recovery for investigational drugs is of concern with regard to the newness criterion. Although a sponsor (for example, a drug manufacturer) may not commercially distribute an investigational drug, in certain circumstances, a sponsor of a clinical trial or an expanded access program may receive authorization from FDA to charge for certain costs associated with making an investigational drug available. The applicant has been authorized to recover certain costs by making Voraxaze® available since 2007. As we stated earlier, once CMS has recalibrated the DRGs based on available data to reflect the costs of an otherwise new technology, that technology will no longer be considered ''new''' for the purposes of the new technology add-on payments. It is possible that a hospital may have submitted a claim to Medicare for the cost of Voraxaze® provided through the applicant's expanded access program. Therefore, it is also possible that the costs associated with this technology may already be reflected in some limited fashion in the data used to determine the MS–DRG relative weights. While these are possibilities, we have not in the past been confronted with a situation where an applicant has indicated that hospitals have sought cost recovery for their technology when the technology was available through the expanded access program. We also have not been confronted with a situation where an applicant has indicated that cost recovery was sought for technologies (that were not available via an expanded access program) during clinical trials. We note that our data do not distinguish charges for drugs by FDA approval status, and, therefore, we do not exclude from the relative weight calculation costs (as derived from charges) associated with investigational drugs if they are included by hospitals on a claim. Therefore, cost data for non-FDA approved technologies (that is, still involved in clinical trials) may be present in the relative weights on a very limited basis prior to FDA approval, regardless of whether a technology received new technology add-on payments.

We are inviting public comment regarding the issue of whether a drug is considered ''new'' for the purposes of new technology add-on payments starting with its availability in the expanded access program, and how that may differ from devices being considered ''new'' starting from the date the device received FDA approval under a HDE (subject to market availability or availability to Medicare beneficiaries) and specifically request comment on these considerations in the context of Voraxaze®. We also are inviting public comment on whether the costs of Voraxaze®, or more generally, any unapproved investigational drug for which cost recovery is authorized are already included in data used to determine relative weights, and how that influences the start of a newness period, if at all. In addition, we are inviting public comment regarding the market availability of Voraxaze® between its FDA approval date of January 17, 2012, and the market availability date according to the applicant of April 2012 and the reasons for the delay in availability.

The applicant submitted a request to the ICD–9–CM Coordination and Maintenance Committee for a new procedure code, which was discussed at the committee's March 2012 meeting. For further information regarding the code proposal, we refer readers to the following CMS Web site: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*.

We are inviting public comment on whether or not Voraxaze® meets the newness criterion, especially in light of its reported availability date through the applicant's expanded access program, and the ability for the applicant to charge for certain costs associated with making an investigational drug available. In addition, we are inviting public comment on considerations that should be given in regard to the technology's delay in availability after FDA's approval was granted, in addition to the reason for the delay, as it relates to the newness criterion.

With respect to cost criterion, the applicant researched the 2009 Standard Analytic Inpatient File (SAF) for cases with a principal or secondary diagnosis of osteosarcoma (ICD–9–CM code series 170.xx), acute lymphoblastic leukemia (ICD–9–CM code series 204.0x), non-Hodgkin's lymphoma (ICD–9–CM code series 200.xx and 202.xx), or primary CNS lymphoma (ICD–9–CM code series 200.5x) with a corresponding ICD–9–CM procedure code for chemotherapy (99.25) that may be eligible for Voraxaze®, based on the product's approved indications. The applicant's search yielded potentially eligible cases within 249 MS–DRGs, of which 56 MS–DRGs captured 12 or more cases.

Using this universe of cases (249 MS–DRGs), the applicant added the additional costs of Voraxaze® to the case-weighted average standardized charge per case. Although the applicant submitted data related to the estimated cost of Voraxaze®, the applicant noted that the cost of the technology was proprietary information. According to the applicant, it did not convert the costs to charges for this analysis because of the technology's high cost. The applicant maintains that an average adult receiving treatment for one of the diagnoses above would require a minimum of four vials of Voraxaze®.

The applicant used the following multiple analysis of different subsets of MS–DRGs to compare the average case-weighted standardized charge per case to the average case-weighted threshold to determine that Voraxaze® met the cost criteria:

- The applicant found 12,324 eligible cases within 249 MS–DRGs, and determined a case-weighted average standardized charge per case of $87,582 (which includes the cost of Voraxaze®) and a case-weighted threshold of $39,216. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.
- The applicant excluded those MS–DRGs that had fewer than 11 cases, which resulted in 12,134 eligible cases within 56 MS–DRGs. The applicant determined a case-weighted average standardized charge per case of $84,039 (which includes the cost of Voraxaze®) and a case-weighted threshold of $37,195. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.
- The applicant analyzed the 20 MS–DRGs that contained the highest number of cases and, based on the 20 cases they stated they found, determined a case-weighted average standardized charge per case of $80,400 (which includes the cost of Voraxaze®) and a case-weighted threshold of $34,990. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.

We are inviting public comment on whether or not Voraxaze® meets the cost criterion. Specifically, we welcome public comment on the methodologies used in the applicant's analysis, including (1) the methods used to identify the eligible cases used in the cost analysis of this technology, especially if there are cases that should be excluded from the analysis because of clinical reasons, and if there are other ways to identify cases for which this technology may be appropriate, and (2) the appropriateness of not converting the costs to charges for the purposes of this analysis and what would be an accurate and appropriate CCR for this technology.

With regard to substantial clinical improvement, the applicant maintains that Voraxaze® is a clinical improvement compared to current treatment options because it is less time intensive, allows certain patient populations to avoid risks associated with current treatment options, and has characteristics that allows it to reduce MTX concentrations more effectively. As noted above, the applicant maintains that current treatment options for renal impairment as a result of toxic MTX concentrations are limited to extracorporeal methods that are time-intensive and could subject patients in certain populations to harm from the associated risks. The applicant states that the administration of Voraxaze® to patients who have been diagnosed with HDMTX-induced renal dysfunction metabolizes circulating MTX to the inactive metabolite DAMPA. The applicant asserts that this characteristic action of the technology represents a substantial clinical improvement over current treatment options available to patients who have toxic MTX concentrations in a more effective, and rapid way, and provides protection to eligible patient populations against potential harm associated with current treatment options.

In addition, the applicant provided the results from a study of 23 patients diagnosed with MTX-induced renal dysfunction treated with Voraxaze®. During this study, the applicant reported that the administration of Voraxaze® lowered toxic MTX concentrations in patients within 15 minutes after the administration by more than 98 percent. Because the administration of Voraxaze® could metabolize both leucovorin and its active metabolite, 5-mTHF, these patients were also administered Thymidine, a drug used to enhance the treatment for patients with high levels of MTX. The applicant notes that the combination of Voraxaze® and Thymidine rescue was well tolerated by the 23 patients studied, and MTX-related toxicities were reduced from severe to mild to moderate. The range of age of these 23 patients was 19 to 94 years old. The applicant asserts that the types of health conditions treated with HDMTX, such as acute lymphoblastic leukemia, osteosarcoma, central nervous system (CNS) lymphoma, and leptomeningeal cancer, tend to occur within the Medicare population and cites research that states ''HD–MTX-induced renal failure with persistence of toxic blood MTX levels is a rare but life threatening complication that occurs more frequently in adults, particularly those with advanced age and CNS lymphoma.'' [18] When these malignancies arise which require treatment with HDMTX, HDMTX-induced renal failure with persistent toxic MTX levels is a complication that occurs more frequently in adults. The applicant asserts that the administration of Voraxaze® has been shown to be well-tolerated by older adult patients, while achieving similar reduction rates in younger patient populations who have been diagnosed with toxic MTX concentrations and treated with Voraxaze®.[19] The applicant also provided additional published peer-reviewed articles [20,21,22,23,24,25] relevant to their application to support their

[18] Schwartz, Borner *et al.,* The Oncologist, December 2007.

[19] Schwartz, Borner *et al.*, The Oncologist, December 2007.

[20] Levy CC, Goldman P. The enzymatic hydrolysis of methotrexate and folic acid. J Biol Chem. 1967; 242:2993–2998.

[21] Minton NP, Atkinson T, Sherwood RF. Molecular cloning of the Pseudomonas carboxypeptidase G2 gene and its expression in Escherichia coli and Pseudomonas putida. J Bacteriol. 1983; 156: 1222–1227.

[22] Widemann BC, Balis FM, Kim A, *et al.* Glucarpidase, leucovorin and thymidine for high-dose methotrexate induced renal dysfunction. Clinical and pharmacologic factors affecting outcome. J Clin Oncology 2010; 28:1–8.

[23] Patterson DM, Lee SM. Glucarpidase following high-dose methotrexate: Update on development. Expert Opin Biol Ther. 2010;10(1):105–111.

[24] Phillips M, Smith W, Balan G, *et al.* Pharmacokinetics of glucarpidase in subjects with normal and impaired renal function. J Clin Pharmacol 2008; 48:279–284.

[25] Bleyer WA. Methotrexate: Clinical pharmacology, current status and therapeutic guidelines. Cancer Treat Rev. 1977;4:87–101.

assertion that they meet the substantial clinical improvement criteria.

We are inviting public comment on whether or not Voraxaze® meets the criterion of representing a substantial clinical improvement for Medicare beneficiaries.

b. DIFICID™ (Fidaxomicin) Tablets

Optimer Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2013 for the use of DIFICID™ (Fidaxomicin) tablets. The applicant asserts that Fidaxomicin is a major clinical advancement in the options available to treat *Clostridium difficile*-associated diarrhea (CDAD).

Clostridium difficile (*C. Diff.*) is a bacterium that can cause infection with symptoms that range from diarrhea to life-threatening inflammation of the colon, and is also commonly referred to as CDAD. The symptoms associated with CDAD can be treated by stopping administration of an antibiotic because often antibiotics can alter the native intestinal microflora and thus trigger CDAD. For mild cases of CDAD, this step may be sufficient to relieve the associated symptoms. However, many patients who have been diagnosed with more severe cases of CDAD require further treatment. Further treatment options include prescribing antibiotics such as Metronidazole or Vancomycin, prescribing probiotics administered in conjunction with antibiotics, and performing surgery using a fecal transplant to restore healthy intestinal bacteria by placing donor stool in the colon. According to the applicant, about one-fourth of the patients diagnosed with CDAD experience a recurrence of these associated symptoms.

As indicated on the labeling submitted to the FDA, the applicant noted that Fidaxomicin is taken twice a day as a daily dosage (200 mg tablet twice daily = 400 mg per day) as an oral antibiotic. The applicant asserts that Fidaxomicin provides potent bactericidal activity against *C. Diff.,* and moderate bactericidal activity against certain other gram-positive organisms, such as enterococcus and staphylococcus. Unlike other antibiotics used to treat CDAD, the applicant noted that the effects of Fidaxomicin preserve bacteroides organisms in the fecal flora. These are markers of normal anaerobic microflora. The applicant asserts that this helps prevent pathogen introduction or persistence, which potentially inhibits the re-emergence of *C. Diff.,* and reduces the likelihood of overgrowths as a result of vancomycin-resistant Enterococcus (VRE). Because of this narrow spectrum of activity, the applicant asserts that Fidaxomicin does not alter this native intestinal microflora.[26]

With regard to the newness criterion, Fidaxomicin was approved by the FDA on May 27, 2011, for the treatment of CDAD in adult patients, 18 years of age and older. Fidaxomicin was commercially available on the market within 7 weeks after the FDA's approval was granted. Currently, there are not any ICD–9–CM diagnosis or procedure codes that exist to uniquely identify the use of Fidaxomicin, or any oral drug, as a procedure. Optimer has submitted a request to the ICD–9–CM Coordination and Maintenance Committee for a new ICD–9–CM procedure code, which was discussed at the committee's meeting on March 5, 2012. For further information regarding the code proposal, we refer readers to the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.*

We believe that under our current new technology add-on payment policy, eligibility for consideration for new technology add-on payments is limited to new technologies associated with procedures described by ICD–9–CM codes. In the FY 2002 IPPS final rule, we establish the framework for our current policy (66 FR 46907 through 46915). The discussion of technologies in that rule focuses on those technologies identifiable by ICD–9–CM codes. We also discuss in response to comments the feasibility and appropriateness of HCPCS codes and V-codes. Similar to ICD–9–CM codes, HCPCS codes are also a procedure-based system and identify procedures. We noted in that rule that V-codes would not be appropriate to use for identification of new technology because they are not a substitute for procedure coding. Volume 3 of ICD–9–CM contains codes that describe inpatient procedures (65 FR 50325). In other words, we have not considered drugs that are only taken orally to be eligible for consideration for new technology add-on payments, because there is no procedure associated with these drugs and, therefore, no ICD–9–CM code(s).

This interpretation is also consistent with other Medicare payment policies. For example, when drugs taken orally are given as part of an outpatient encounter, they would likely be considered self-administered drugs under the Hospital Outpatient Prospective Payment System (OPPS). If a Medicare beneficiary who has outpatient status were to be provided a self-administered drug by a hospital or wholly-owned or wholly-operated entity of that hospital and that beneficiary were subsequently admitted to that hospital for a related reason within three days, the hospital may not include these self-administered drugs on the inpatient bill (under the 3-day payment window policy), because self-administered drugs are not covered under the OPPS. However, they would be required to include nondiagnostic services related to admission and all other diagnostic services on the inpatient bill (under the 3-day payment window).

We are inviting public comment on our interpretation of our policy regarding drugs that are only self-administered for consideration for new technology add-on payments. Further, we are inviting public comment on whether or not Fidaxomicin meets the newness criterion.

With regard to the cost criterion, Optimer researched the FY 2010 MedPAR file for cases that would be eligible for treatment with Fidaxomicin to determine it if would qualify for the cost criterion for new technology add-on payments. Based on its analysis, the applicant identified cases in which a patient had been diagnosed with CDAD by searching the MedPAR file for claims that included ICD–9–CM diagnosis code 008.45 (Intestinal infection due to *Clostridium difficile*) as a principal diagnosis or secondary diagnosis. Optimer provided three examples of how the results of the analyses of different MS–DRGs demonstrate that it meets the cost criterion.

Under the first analysis, the applicant researched the FY 2010 MedPAR file for cases that included ICD–9–CM diagnosis code 008.45 as a principal or secondary diagnosis across all MS–DRGs. The applicant found 162,310 cases within 536 MS–DRGs, and determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $50,136. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical Consumer Price Index (CPI), the applicant determined a case-weighted standardized charge per case that equals $53,394. The applicant then added the charges related to the technology to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $58,994, which exceeds the

[26] Koo, Garey *et al.* Future novel therapeutic agents for Clostridium difficile infection. Expert Opin Investig Drugs, 2010;19(7):825–836. Tannock, Munro *et al.,* A new macrocyclic antibiotic, fidaxomicin (OPT–80), causes less alteration to the bowel microbiota of Clostridium difficile-infected patients than does vancomycin. Microbiology. 2010 Nov;156(Pt 11):3354–9.

case-weighted threshold of $43,673. Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this first analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Under the second analysis, the applicant researched the FY 2010 MedPAR file for cases that included ICD–9–CM diagnosis code 008.45 only as a principal diagnosis, which mapped to MS–DRGs 371 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC), 372 (Major Gastrointestinal Disorders and Peritoneal Infections with CC), and 373 (Major Gastrointestinal Disorders and Peritoneal Infections without CC/MCC). The applicant found 55,410 cases, and determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $28,007. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical CPI, the applicant determined a case-weighted standardized charge per case that equals $29,828. The applicant then added the charges related to the drug to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $35,428, which exceeds the case-weighted threshold of $34,730. Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this second analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Under the third analysis, the applicant again researched the FY 2010 MedPAR file for cases that included ICD–9–CM diagnosis code 008.45 as a principal or secondary diagnosis across all MS–DRGs. The applicant then narrowed the results of the analysis to include only the top 37 MS–DRGs (in volume of cases), which accounted for 75 percent of all cases. The applicant's methodology resulted in 121,748 cases, and the applicant determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $45,523. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical CPI, the applicant determined a case-weighted standardized charge per case that equals $48,482. The applicant then added the charges related to the drug to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $54,082, which exceeds the case-weighted threshold of $42,452. Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this third analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

In the three analyses discussed above, the applicant submitted data related to the estimated cost and charge of the drug (using a charge markup). However, the applicant has not released the cost of the technology, asserting that it is proprietary information. The applicant converted the cost of the technology to a charge using a charge markup (a factor of 6.5 percent based on the Medical CPI) that represented a 10-day dosage.

We are concerned that these analyses do not take into account situations in which patients would be prescribed Fidaxomicin later in the duration of their inpatient stay, and may finish the course of Fidaxomicin sometime after being discharged from the hospital. In addition, as discussed above, if Fidaxomicin is prescribed and self-administered during the 3-day period prior to admission to an IPPS hospital for a related encounter, we do not believe that this service is payable under the OPPS, nor that it can be included on the inpatient claim submitted to Medicare because of the 3-day payment window policy. Therefore, it may not be appropriate to include in the applicant's calculations the full charges related to Fidaxomicin and the corresponding proprietary charges for the 10-day dose. In addition, we believe that it is necessary for the applicant to adjust its estimates to remove from the MedPAR file's claims for the charges that describe other types of treatment options such as Vancomycin, since use of these treatments would preclude use of Fidaxomicin. Furthermore, to identify the cases that may be eligible for the technology's use, the applicant researched and analyzed claims that included ICD–9–CM diagnosis code 008.45 as the principal diagnosis or as the principal or secondary diagnosis. We are concerned that this baseline for eligible cases may not represent the appropriate universe of cases, such as if all MS–DRGs were considered or if a subset of MS–DRGs were considered.

We are inviting public comment on whether or not Fidaxomicin meets the cost criterion. In addition, we are inviting public comment on the methodologies used by the applicant in its analyses, in particular the assumptions made about the dosage in developing the cost analysis. We also are interested in comments about the applicant's selection of claims with an ICD–9–CM diagnosis code 008.45 as the principal diagnosis or secondary diagnosis, and whether those cases accurately represent the Medicare population that may benefit from the technology's use.

With regard to the substantial clinical improvement criterion, the applicant maintains that Fidaxomicin represents a substantial clinical improvement to the treatment options currently available. According to the applicant, Fidaxomicin represents the first major clinical advancement in the treatment options available to address CDAD in more than 25 years, and it is one of only two agents indicated by the FDA to treat this condition. The applicant notes that reports from its clinical trials show that a higher proportion of patients achieve positive clinical response to treatment with Fidaxomicin as opposed to treatment with Vancomycin. The applicant reported that these patients did not experience recurrences of associated symptoms for at least 25 days after the end of treatment. The applicant asserts that Fidaxomicin has longer acting antimicrobial activity and inhibits spore production in *C. difficile* in vitro. The applicant stated that *C. difficile* cells produce spores when exposed to air; therefore, transmission of infection occurs even when the cells themselves are killed.

The applicant reported on two randomized, double-blinded trials [27,28]. A non-inferiority design was utilized to demonstrate the efficacy of administering Fidaxomicin (200 mg twice daily for 10 days) compared to administering Vancomycin (125 mg four times daily for 10 days) to adult patients diagnosed with CDAD. The demographic profile and baseline CDAD characteristics of the subjects enrolled in both trials were similar. These patients had a median age of 64 years, were mainly white (90 percent), female (58 percent), and inpatients (63 percent).

The applicant reported that the primary efficacy endpoint (for both trials) was the clinical response rate at

[27] Pivotal trial 101.1.C.003:

Thomas J. Louie, M.D., Mark A. Miller, M.D., Kathleen M. Mullane, D.O., Karl Weiss, M.D., Arnold Lentnek, M.D., Yoav Golan, M.D., Sherwood Gorbach, M.D., Pamela Sears, Ph.D., and Youe-Kong Shue, Ph.D. for the OPT–80–003 Clinical Study Group. *Fidaxomicin versus Vancomycin for Clostridium difficile Infection. N Engl J Med* 2011; 364:422–431 February 3, 2011. *Attached reference: 12_LouieNEJM2011.pdf.*

[28] Crook D, Weiss K, Comely O, Miller M, Esposito R, Gorbach 8. Randomized Clinical Trial (RCT) in *Clostridium difficile* Infection (CDI) Confirms Equivalent Cure Rate and Lower Recurrence Rate of Fidaxomicin (FDX) versus Vancomycin (VCN). 20th European Congress of Clinical Microbiology and Infectious Diseases; April 10–13, 2010; Vienna, Austria.

the end of therapy, based upon improvement in diarrhea or other symptoms such that, in the investigator's judgment, further CDAD treatment was not needed. An additional efficacy endpoint was sustained clinical response 25 days after the end of treatment. Sustained response was only evaluated for patients who were clinical successes at the end of treatment. Sustained response was defined as clinical response at the end of treatment, and survival without proven or suspected reoccurrence of a diagnosis of CDAD beyond 25 days after the end of treatment. The results for clinical response at the end of treatment in both trials, which the applicant submitted in the table below, indicate that the effects of administering Fidaxomicin is noninferior to the effects of administering Vancomycin based on the 95 percent confidence interval (CI) lower limit being greater than the non-inferiority margin of −10 percent.

The applicant stated that the results for sustained clinical response at the end of the follow-up period, also shown in the table below, indicate that the effects of administering Fidaxomicin is superior to the effects of administering Vancomycin on this endpoint. Because clinical success at the end of treatment and mortality rates were similar across treatment arms (approximately 6 percent in each group), the applicant determined that the differences in sustained clinical response were due to lower rates of proven or suspected reoccurrence of diagnoses of CDAD in patients during the follow-up period. In addition, the applicant asserts that the effects of administering Fidaxomicin has minimal impact on normal gut flora due to its limited specificity, and could be associated with a lower risk of acquisition of VRE if used as a treatment option instead of administering Vancomycin.

CLINICAL RESPONSE RATES AT END-OF-THERAPY AND SUSTAINED RESPONSE AT 25 DAYS POST-THERAPY

	Clinical response at end of treatment			Sustained response at follow-up		
	FIDAXOMICIN % (N)	Vancomycin % (N)	Difference (95% CI)	FIDAXOMICIN % (N)	Vancomycin % (N)	Difference (95% CI)
Trial 1	88% (N = 289)	86% (N = 307)	2.6% (−2.9%, 8.0%)	70% (N = 289)	57% (N = 307)	12.7% (4.4%, 20.9%)
Trial 2	88% (N = 253)	87% (N = 256)	1.0% (−4.8%, 6.8%)	72% (N = 253)	57% (N = 256)	14.6% (5.8%, 23.3%)

Based on the analysis described above, the applicant asserts Fidaxomicin meets the substantial clinical improvement criterion as a treatment option with the potential to decrease hospitalizations and physician office visits, as well as to improve the quality of life for patients who have been diagnosed with CDAD.

We are concerned that this technology may not offer a substantial clinical improvement compared to other effective treatment alternatives already available in the treatment of patients who have been diagnosed with CDAD. In addition, although the applicant maintains that there is no evidence of significant clinical resistance developing with the use of this drug, we are still concerned about the long-term possibility that patients may develop resistance to this drug since the applicant provided no data to substantiate its claim. We are inviting public comment on whether or not Fidaxomicin meets the substantial clinical improvement criterion based on the analysis and results presented by the applicant.

c. Zilver® PTX® Drug Eluting Stent

Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Stent (Zilver® PTX®) for FY 2013. The Zilver® PTX® is intended for use in the treatment of peripheral artery disease (PAD) of the above–the-knee femoropopliteal arteries (superficial femoral arteries). According to the applicant, the stent is percutaneously inserted into the artery(s), usually by accessing the common femoral artery in the groin. The applicant states that an introducer catheter is inserted over the wire guide and into the target vessel where the lesion will first be treated with an angioplasty balloon to prepare the vessel for stenting. The applicant indicates that the stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel. Paclitaxel is a drug approved for use as an anticancer agent and for use with coronary stents to reduce the risk of renarrowing of the coronary arteries after stenting procedures.

The manufacturer maintains that there are currently no FDA approved drug-eluting stents used for superficial femoral arteries. The applicant expects to receive FDA approval for the stent in the second quarter of 2012. The technology is currently described by ICD–9–CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery). We are inviting public comment regarding how the Zilver® PTX® meets the newness criterion.

With regard to the cost criterion, the applicant believes that cases of superficial femoral arteries typically map to MS–DRGs 252 (Other Vascular Procedures with MCC), 253 (Other Vascular Procedures with CC), and 254 (Other Vascular Procedures without CC/MCC). The applicant searched the FY 2009 MedPAR file for cases with a procedure code of 39.90 (Insertion of non-drug-eluting peripheral vessel stents) in combination with a diagnosis code of 440.20 (Atherosclerosis of the extremities, unspecified), 440.21 (Atherosclerosis of the extremities, with intermittent claudication), 440.22 (Atherosclerosis of the extremities with rest pain), 440.23 (Atherosclerosis of the extremities with ulceration), and 440.24 (Atherosclerosis of the extremities with gangrene). The applicant found 7,144 cases (or 24.4 percent of all cases) in MS–DRG 252; 9,146 cases (or 31.2 percent of all cases) in MS–DRG 253; and 13,012 cases (or 44.4 percent of all cases) in MS–DRG 254. The average charge per case was $78,765 for MS–DRG 252, $63,758 for MS–DRG 253, and $47,586 for MS–DRG 254, equating to a case-weighted average charge per case of $60,236.

The case-weighted average charge per case above does not include charges related to the Zilver® PTX®; therefore, it is first necessary to remove the amount of charges related to the nondrug-eluting peripheral vessel stents and replace them with charges related to the Zilver® PTX®. The applicant used two methodologies to remove the charges of the nondrug-eluting peripheral vessel stents and replace them with charges related to the Zilver® PTX®. Although the applicant submitted data related to the estimated cost of the nondrug-eluting peripheral vessel stents and the Zilver® PTX®, the applicant noted that the cost of these devices was proprietary information.

Under the first methodology, the applicant determined the amount of

stents per case based on the following ICD–9–CM codes on each claim: 00.45 (Insertion of one vascular stent), 00.46 (Insertion of two vascular stents), 00.47 (Insertion of three vascular stents) and 00.48 (Insertion of four or more vascular stents). If a claim had a code of 00.48, the applicant assumed a maximum of four stents per case. The applicant multiplied the amount of stents used per case by the average market price for nondrug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing the results by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case and then standardized the charges per case. Because the applicant used FY 2009 MedPAR data, it was necessary to inflate the charges from FY 2009 to FY 2012. Using data from the U.S. Department of Labor Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 6 percent. To determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD–9–CM codes above, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study.[29] The applicant believed that it is appropriate to use data from the clinical study (to determine the average amount of stents used per case) rather than the actual data from the claims because the length of a nondrug-eluting peripheral vessel stent typically ranges from 80mm to 120 mm, while the length of the Zilver® PTX® is 80 mm (which could cause a variance in the actual amount of stents used per case when using the Zilver® PTX®). Similar to above, the applicant multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the national average CCR of 0.329 for supplies and equipment. The applicant then added the amount of charges related to the Zilver® PTX® to the inflated average standardized charge per case and determined a final case-weighted average standardized charge per case of $60,014. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $52,293 (all calculations above were performed using unrounded numbers). Because the case-weighted average standardized charge per case for the applicable MS–DRGs exceed the case-weighted threshold amount, the applicant maintains that the Zilver® PTX® meets the cost criterion.

The second methodology was similar to the first methodology described above, but the applicant used hospital-specific CCRs from the FY 2009 IPPS impact file to convert the cost of the nondrug-eluting peripheral vessel stents and the cost of the Zilver® PTX® to charges. In summary, the applicant determined the amount of nondrug-eluting peripheral vessel stents used per case based on the ICD–9–CM codes on each claim (as discussed above). The applicant multiplied the amount of stents used per case by the average market price for nondrug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing by the hospital-specific CCR (from the FY 2009 IPPS impact file). The applicant removed the appropriate amount of charges per case and then standardized the charges per case. Similar to the step described above, because the applicant used FY 2009 MedPAR data, it was necessary to inflate the charges from FY 2009 to FY 2012. Using data from the Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 6 percent. To determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD–9–CM codes above, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study (because of the reason stated in the first methodology). The applicant then multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the hospital-specific CCR (from the FY 2009 IPPS impact file). The applicant then added the amount of charges related to the Zilver® PTX® to the inflated average standardized charge per case and determined a final case-weighted average standardized charge per case of $60,339. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $52,293 (all calculations above were performed using unrounded numbers). Because the case-weighted average standardized charge per case for the applicable MS–DRGs exceed the case-weighted threshold amount, the applicant maintains that the Zilver® PTX® would meet the cost criterion.

We are inviting public comment on whether or not the Zilver® PTX® meets the cost criterion. Additionally, we are inviting public comment on the methodologies used by the applicant in its analysis, including its assumptions regarding the types of cases in which this technology could potentially be used, the number of stents required for each case, and the CCRs used in the cost calculation.

In an effort to demonstrate that the technology meets the substantial clinical improvement criterion, the applicant shared several findings from the clinical trial data. The applicant stated that current treatment options for patients who have been diagnosed with PAD includes angioplasty, bare metal stenting, bypass graft and endarterectomy. The applicant asserts that the Zilver® PTX® meets the substantial clinical improvement because it decreases the recurrence of symptoms arising from restenotic SFA lesions, the rate of subsequent diagnostic or therapeutic interventions required to address restenotic lesions, and the number of future hospitalizations.

The applicant cited a 480-patient, multicenter, multinational randomized controlled trial that compared the Zilver® PTX® to balloon angioplasty; an additional component of the study allowed a direct comparison of the Zilver® PTX® to a bare (uncoated) metal Zilver® stent. The primary safety endpoint of the randomized controlled study was ''Event-Free Survival'' (EFS), defined as ''freedom from the major adverse events of death, target lesion revascularization, target limb ischemia requiring surgical intervention or surgical repair of the target vessel, and freedom of worsening systems as described by the Rutherford classification by 2 classes or to class 5 or 6.'' The primary effectiveness endpoint was primary patency (defined as a less than 50 percent renarrowing).

The applicant noted that the Zilver® PTX® had an EFS of 90.4 percent compared to balloon angioplasty, which had an EFS of 83.9 percent, demonstrating that the Zilver® PTX® is as safe or safer than balloon angioplasty. In addition, the applicant noted that the Zilver® PTX® demonstrated a 50-percent reduction in restenosis rates compared to angioplasty and a 20-percent reduction compared to bare metal stents. The 12-month patency rate

[29] Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S.(2011), Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month zilver PTX randomized study results. Circulation Cardiovascular Interventions, published online September 27, 2011, 495–504.

for the Zilver® PTX® was 83.1 percent, which compared favorably to the balloon angioplasty patency rate of 32.8 percent. In the provisional stenting arm of the study, which allowed a direct comparison of the Zilver® PTX® and a bare metal stent, the Zilver® PTX® primary patency exceeded the bare metal stent patency by nearly 20 percent (89.9 percent versus 73.0 percent). The applicant stated that these differences are significant, as they result in a substantial clinical improvement compared to angioplasty and bare metal stenting, with patients being spared a recurrence of their leg pain and the need to be admitted to the hospital for repeat procedures on these treated lesions.

The applicant also cited a prospective, multicenter, multinational, 787-patient single arm study on the Zilver® PTX® that demonstrated similar safety and effectiveness results consistent with those from the pivotal randomized controlled study above. The applicant cited an EFS for the Zilver® PTX® of 89.0 percent and an 86.2 percent primary patency rate. The applicant stated that these results confirm the safety and effectiveness of the Zilver® PTX®, and compare favorably to current results for angioplasty and bare metal stenting. The applicant added that these results also demonstrate a 67 to 81 percent relative reduction in Target Lesion Revascularization (the need to retreat an already treated lesion that has restenosed, resulting in a recurrence of symptoms) rates compared to recently published results of contemporary bare metal stents.[30]

We are inviting public comment regarding whether the Zilver® PTX® meets the substantial clinical improvement criterion.

d. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft (Zenith® F. Graft) for FY 2013. The applicant stated that the current treatment for patients who have had an AAA is an endovascular graft. The applicant explained that the Zenith® F. Graft is an implantable device designed to treat patients who have an AAA and who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The applicant noted that, currently, an AAA is treated through an open surgical repair or medical management for those patients not eligible for currently approved AAA endovascular grafts.

The applicant stated that the Zenith® F. Graft is custom-made for each patient. It is a modular system consisting of three components: a two-part main body graft and one iliac leg. The two-part main body of the graft consists of a proximal tubular graft and a distal bifurcated graft body. The proximal body graft contains precisely located holes (fenestrations) and/or cut-outs from the proximal margin (scallops) of the polyester graft material along with a bare proximal stent with barbs to provide fixation. The iliac leg component, which couples with the main bifurcated body, completes the basic fenestrated endograft.

With respect to newness, the applicant stated that FDA approval for the use of the Zenith® F. Graft was granted on April 4, 2012. The technology is described by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta), which became effective October 1, 2011. While procedure code 39.78 maps to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without MCC/CC, respectively), the applicant believes that MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) would be a more appropriate assignment for procedure code 39.78. (We note that in section III.G.3.b. of this preamble, we discuss our response to the request for consideration of MS–DRGs 237 and 238 as a more appropriate assignment for procedure code 39.78.) We are inviting public comment regarding whether the Zenith® F. Graft meets the newness criterion for new technology add-on payment.

With regard to the cost criterion, the applicant used clinical trial data and three separate analyses of FY 2010 MedPAR data to demonstrate that the Zenith® F. Graft meets the cost criteria. The clinical trial data[31] was based on 173 claims (all Medicare patients except one patient). The applicant found that, of the 173 cases, 35 cases (or 20.2 percent of all cases) mapped to MS–DRG 252, 86 cases (or 49.7 percent of all cases) mapped to MS–DRG 253, and 52 cases (or 30.1 percent of all cases) mapped to MS–DRG 254, equating to a case-weighted average charge per case of $87,733.

The applicant noted that the investigational devices (the bare metal renal stents that are used in the procedure and the Zenith® F. Graft) were sold to the trial sites at reduced prices. Therefore, the average charge per case cited above contains reduced charges for the investigational devices rather than commercial charges. As a result, the applicant believes it is necessary to remove the reduced charges for the investigational devices and replace them with commercial charges, in order to determine the cost of the investigational devices for each of the three analyses. Although the applicant submitted data related to the estimated cost of the investigational devices, the applicant noted that the cost of these devices was proprietary information.

To remove the reduced charges for the investigational devices, the applicant searched the clinical trial claims data and removed those charges with a revenue code of 0624 (investigational device exempt). Because the claims data for the clinical trial ranged from 2002 to 2010, it was necessary to inflate the charges. Using data from the U.S. Department of Labor Bureau of Labor Statistics (BLS) Consumer Price Index, the applicant applied an inflation factor to the claim charges ranging from 3 percent to 27 percent, depending on the year of the claim. After inflating the charges, the applicant then added the commercial charges of the investigational devices to the inflated charge per case. To determine the amount of commercial charges related to the investigational devices, the applicant divided the cost of the investigational devices by the hospital-specific CCR from the FY 2012 IPPS Final Rule Impact File. After adding the charges of the investigational devices to the inflated charges, the applicant then standardized the charges on each claim. As a result, the applicant determined a final case-weighted average standardized charge per case of $122,821. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $53,869 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount, the applicant maintains that the Zenith® F.

[30] Dake, M. D., Scheinert, D., Tepe, G., Tessarek, J., Fanelli, F., Bosiers, M., *et al.* (2011). Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: Twelve-month safety and effectiveness results from the zilver PTX single-arm clinical study. *Journal of Endovascular Therapy, 18(5),* 613–623.

[31] Evaluation of the Safety and Effectiveness of the Zenith(R) Fenestrated AAA Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft Pivotal Study, Clinicaltrials.gov: Identifier NCT00875563 and a Physician Sponsored IDE.

Graft meets the cost criterion for new technology add-on payment.

We note that, in addition to the analysis above, the applicant conducted a similar cost analysis using drug eluting renal stents instead of bare metal renal stents. The applicant noted that the price of drug eluting renal stents exceeds the price of bare metal renal stents by approximately $2,200 per stent. Therefore, the applicant asserted that if the price of drug eluting renal stents is more expensive than bare metal renal stents and the Zenith® F. Graft meets the cost criteria with bare metal renal stents, the Zenith® F. Graft also meets the cost criteria when the applicant uses drug eluting renal stents in its analysis.

As mentioned above, the applicant conducted three separate analyses using FY 2010 MedPAR data to identify cases eligible for the Zenith® F. Graft to demonstrate that it meets the cost criterion. Cases of endovascular implantation of branching or fenestrated graft(s) in the aorta are coded with procedure code 39.78, which currently map to MS–DRGs 252, 253, and 254. Because procedure code 39.78 was effective October 1, 2011, the applicant noted that it was unable to conduct a MedPAR data analysis with claims that contained a procedure code of 39.78. Therefore, in order to identify cases eligible for the Zenith® F. Graft prior to October 1, 2011, the applicant searched the MedPAR file for the following three scenarios. The first analysis searched the FY 2010 MedPAR file for cases with procedure code 39.71 (Endovascular implantation of graft in abdominal aorta) in combination with a diagnosis code of 441.4 (Abdominal aneurysm without mention of rupture). The applicant conducted this analysis using MS–DRGs 237 and 238 rather than MS–DRGs 252, 253, and 254 because procedure code 39.71 maps to MS–DRGs 237 and 238. The applicant found 1,679 cases (or 9.1 percent of all cases) in MS–DRG 237 and 16,793 cases (or 90.9 percent of all cases) in MS–DRG 238. The average charge per case was $122,252 for MS–DRG 237 and $76,883 for MS–DRG 238, equating to a case-weighted average charge per case of $81,006.

The applicant noted that these MedPAR claims data included charges for the existing stent graft but did not include charges for the Zenith® F. Graft. Therefore, the applicant stated that it was first necessary to remove the amount of charges related to the existing stent graft and replace them with charges for the Zenith® F. Graft. Although the applicant submitted data related to the estimated cost of the existing stent graft and the Zenith® F. Graft, the applicant noted that the cost of these devices was proprietary information.

To determine the amount of charges for the existing stent graft, the applicant divided the costs for the existing stent graft by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. Because the applicant used FY 2010 MedPAR data, it was necessary to inflate the charges from FY 2010 to FY 2012. Using data from the BLS' Consumer Price Index, the applicant inflated the case-weighted average standardized charge per case with an inflation factor of 4 percent. The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. The applicant determined a final case-weighted average standardized charge per case of $80,509. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 237and 238 was $72,512 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount under this first analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payment. The applicant noted that the FY 2013 Table 10 thresholds for MS–DRGs 237 and 238 are much higher than the FY 2013 Table 10 thresholds for MS–DRGs 252, 253, and 254. Therefore, the applicant believes that if the final case-weighted average standardized charge per case exceeds the case-weighted threshold for MS–DRGs 237 and 238, it would exceed any case-weighted threshold for MS–DRGs 252, 253, and 254.

For their second analysis, the applicant searched the FY 2010 MedPAR file for cases with procedure code 38.44 (Resection of vessel with replacement, aorta) in combination with a diagnosis code of 441.4. Similar to the first analysis, the applicant conducted this analysis using MS–DRGs 237 and 238 rather than MS–DRGs 252, 253, and 254 because procedure code 38.44 maps to MS–DRGs 237 and 238. The applicant found 1,310 cases (or 37.9 percent of all cases) in MS–DRG 237 and 2,145 cases (or 62.1 percent of all cases) in MS–DRG 238. The average charge per case was $110,708 for MS–DRG 237 and $64,095 for MS–DRG 238, equating to a case-weighted average charge per case of $81,769.

The next steps of the applicant's second analysis were similar to the steps in the first analysis. The applicant noted that the MedPAR claims data included charges for the vascular graft for open procedures but did not include charges for the Zenith® F. Graft. Therefore, the applicant indicated that it was first necessary to remove the amount of charges related to the vascular graft for open procedures and replace them with charges for the Zenith® F. Graft. Although the applicant submitted data related to the estimated cost of the vascular graft for open procedures and the Zenith® F. Graft, the applicant noted that the cost of these devices was proprietary information.

To determine the amount of charges for the vascular graft for open procedures, the applicant divided the costs for the vascular graft for open procedures by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. Similar to the first analysis, the applicant inflated the case-weighted average charge per case with an inflation factor of 4 percent (based on data from the BLS' Consumer Price Index). The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. The applicant determined a final case-weighted average standardized charge per case of $118,774. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 237 and 238 was $81,776 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this second analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payments. As discussed above, the applicant noted that the FY 2013 Table 10 thresholds for MS–DRGs 237 and 238 are much higher ($101,728 for MS–DRG 237 and $69,591 for MS–DRG 238) than the FY 2013 Table 10 thresholds for MS–DRGs 252, 253, and 254 ($60,619 for MS–DRG 252, $56,719 for MS–DRG 253 and $44,611 for MS–DRG 254).

Therefore, the applicant believes that if the final case-weighted average standardized charge per case exceeds the case-weighted threshold for MS–DRGs 237 and 238, it would exceed any case-weighted threshold for MS–DRGs 252, 253, and 254.

While the applicant removed charges for the vascular graft for open procedures, we are concerned that the applicant did not remove charges for other services such as extra operating room time and other possible charges that would be incurred during an open procedure but would possibly not be incurred during cases when the Zenith® F. Graft is implanted.

The third analysis was a combination of the first and second analyses discussed above. The applicant searched the FY 2010 MedPAR file for cases with a procedure code of 38.44 or 39.71 in combination with a diagnosis code of 441.4. Similar to the first and second analyses, the applicant conducted this analysis using MS–DRGs 237 and 238 rather than MS–DRGs 252, 253, and 254 because both procedure codes map to MS–DRGs 237 and 238. The applicant found 2,981 cases (or 13.6 percent of all cases) in MS–DRG 237 and 18,928 cases (or 86.4 percent of all cases) in MS–DRG 238. The applicant removed those cases that had both procedure codes 38.44 and 39.71 on the claim. The average charge per case was $116,826 for MS–DRG 237 and $75,298 for MS–DRG 238, equating to a case-weighted average charge per case of $80,948.

The applicant noted that the MedPAR claims data included charges for the existing stent graft or vascular graft for open procedures but did not include charges for the Zenith® F. Graft. Therefore, the applicant stated that it was first necessary to remove the amount of charges related to the existing stent graft or vascular graft for open procedures and replace them with charges for the Zenith® F. Graft. Similar to the first and second analyses, to determine the amount of charges for the existing stent graft or vascular graft for open procedures, the applicant divided the costs for these devices by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. The applicant inflated the case-weighted average standardized charge per case with an inflation factor of 4 percent (based on data from the BLS' Consumer Price Index). The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. As a result, the applicant determined a final case-weighted average standardized charge per case of $86,081. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 237 and 238 was $73,964 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payment. As discussed above, the applicant noted that the FY 2013 Table 10 thresholds for MS–DRGs 237 and 238 are much higher than the FY 2013 Table 10 thresholds for MS–DRGs 252, 253, and 254. The applicant believes that if the final case-weighted average standardized charge per case exceeds the case-weighted threshold for MS–DRGs 237–238, it would exceed any case-weighted threshold for MS–DRGs 252, 253, and 254.

Similar to our concerns with the second analysis, we are concerned that for this third analysis the applicant did not remove charges for other services such as extra operating room time and other possible charges that would be incurred during an open procedure, but would possibly not be incurred during cases when the Zenith® F. Graft is implanted.

We appreciate the multiple analyses of the FY 2010 MedPAR data provided by the applicant and are inviting public comment on whether or not the Zenith® F. Graft meets the cost criterion for new technology add-on payments. In addition, we are inviting public comment on the methodologies used by the applicant, specifically on whether and the degree to which the second and third analyses may contain charges not relevant to the final case-weighted standardized charge per case determined by the applicant.

The applicant maintains that the technology also meets the substantial clinical improvement criterion. The applicant first explained that current treatment for those patients who are not eligible for standard endovascular AAA devices is an open repair. The applicant referenced data from a published series [32] that demonstrated an open repair can lead to a high risk of morbidity and increased mortality. The applicant added that an open procedure requires suprarenal aortic cross-clamping.[33] The applicant also noted that there is a high risk of blood loss during an open procedure and the de-branching of vessels increases the level of surgical risk. The applicant further noted that 30 to 40 percent of patients who have an infrarenal AAA cannot be treated with current commercial devices because of anatomical reasons (for example, insufficient neck length to achieve graft adequate seal). The applicant added that use of standard endografts in patients with neck lengths less than 10 mm can result in a fourfold increase in an endoleak.[34]

The applicant also stated that the intended use of the Zenith® F. Graft differs from standard AAA endovascular grafts in that the fenestrated device provides physicians the ability to treat patients who have infrarenal aortic neck lengths as short as 4 mm, where standard endovascular AAA devices require an infrarenal aortic neck length of at least 10 to 15 mm. Therefore, the applicant believes that the Zenith® F. Graft offers an additional AAA repair option to those patients who have limited surgical treatment options (for example, if short infrarenal neck lengths make the patients at too high a risk to be candidates for open surgical repair).

The applicant also stated, for patients who have AAAs and short infrarenal neck lengths, the Zenith® F. Graft offers a less invasive treatment option than open surgical repair. The applicant referred to several sources of literature to support the following endpoints for fenestrated endovascular aortic repair (EVAR) versus open repair of the juxtarenal AAA relative to open repair of the juxtarenal AAA: Reduced peri-operative mortality (2.4 percent (range: 0 to 5.7 percent)) [35,36,37,38,39,40,41,42,43]

[32] Wilderman, M. *et al.* Fenestrated Grafts or Debranching Procedures for Complex Abdominal Aortic Aneurysms. Perspectives in Vascular Surgery and Endovascular Therapy, March 2009; 21(1): 13–18.

[33] Jongkind V, Yeung K, *et al.* Juxtarenal aortic aneurysm repair. Journal of Vascular Surgery 2010 Sept; 29(3) 760–767.

[34] Amiot, S., *et al.,* Fenestrated endovascular grafting: The French multicentre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 537–44.

[35] Nordon, I.M., *et al.,* Modern treatment of juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair—a systematic review. Eur J Vasc Endovasc Surg, 2009. 38(1): p. 35–41

[36] Verhoeven, E.L., *et al.,* Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: An 8-year single-centre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 529–36.

[37] Chisci E, Kristmundsson T, de Donato G, *et al.* The AAA with a challenging neck: Outcome of open versus endovascular repair with standard and fenestrated stent-grafts. J Endovasc Ther 2009;16:137–146.

Continued

reported for fenestrated EVAR repairs versus 2.9 percent (range 0 to 7.4 percent)[44,45] reported for open repair of juxtarenal AAA);[46] reduced morbidity by reducing renal failure requiring permanent dialysis (1.9 percent (pooled average) for fenestrated EVAR repairs versus 3.4 percent reported for open repair of juxtarenal AAA); shorter hospital stay and less operative blood loss to open repair. The applicant maintains that fenestrated EVAR repair results in an average length of stay of 3.5 days, compared to 14.2 days for open repair of juxtarenal AAA, and blood loss of 537 ml, compared to 2586 ml for open repair of juxtarenal AAA.

We note that the information provided by the applicant to evaluate substantial clinical improvement compares this technology to open surgical repair. We are concerned that the applicant does not present publicly available information comparing the technology to medical management, which the applicant mentions as another method for treating patients anatomically unsuited for currently approved AAA endovascular grafts. In these comparisons, we are also concerned that information regarding the longevity of the Zenith® F. Graft as well as long-term complications and secondary interventions or reinterventions has not been presented. In terms of the data presented by the applicant, we are concerned that these clinical study data were nonrandomized, did not differentiate between patients by infrarenal neck length and/or suitability for other endovascular grafts, and were of noninferiority. We are inviting public comment on whether or not the Zenith® F. Graft meets the substantial clinical improvement criterion.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts ''for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.'' In accordance with the broad discretion conferred under the Act, we currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2013 hospital wage index based on the statistical areas, including OMB's revised definitions of Metropolitan Areas, appears under section III.B. of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act requires that we update the wage index annually. Furthermore, this section of the Act provides that the Secretary base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. The survey must exclude the wages and wage-related costs incurred in furnishing skilled nursing services. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2013 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed below in section III.H. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2013 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply beginning October 1, 2012 (the FY 2013 wage index) appears under section III.F. of this preamble.

In response to concerns frequently expressed by providers and other relevant parties that the current wage index system does not effectively reflect the true variation in labor costs for a large cross-section of hospitals, two studies were undertaken by the Department. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare'' and to ''consult with relevant affected parties.'' Second, the Secretary commissioned the Institute of Medicine (IOM) to ''evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors.'' Reports on both of these studies recently have been released. We refer readers to section IX.B. of this preamble for summaries of the studies, their findings, and recommendations on reforming the wage index system.

B. Core-Based Statistical Areas for the Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with the broad discretion under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we define hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by OMB and announced in December 2003 (69 FR 49027). For a discussion of OMB's delineations of CBSAs and our implementation of the CBSA definitions, we refer readers to the preamble of the FY 2005 IPPS final rule (69 FR 49026 through 49032). We also discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582) that, in 2013, OMB plans to announce new area delineations based on new standards adopted in 2010 (75 FR 37246) and the

[38] Amiot, S., *et al.,* Fenestrated endovascular grafting: The French multicentre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 537–44.

[39] Kristmundsson T, Sonesson B, Malina M, *et al.* Fenestrated endovascular repair for juxtarenal aortic pathology. J Vasc Surg 2009;49:568–574.

[40] Beck AW, Bos WT, Vourliotakis G, *et al.* Fenestrated and branched endograft repair of juxtarenal aneurysms after previous open aortic reconstruction. J Vasc Surg 2009;49:1387–1394.

[41] Tambyraja, A.L., *et al.,* Fenestrated aortic endografts for juxtarenal aortic aneurysm: Medium term outcomes. Eur J Vasc Endovasc Surg, 2011. 42(1): p. 54–8.

[42] Unpublished results, Evaluation of the Safety and Effectiveness of the Zenith(R) Fenestrated AAA Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft Pivotal Study, Clinicaltrials.gov identifier NCT00875563.

[43] Unpublished results, British Society of Endovascular Therapy-sponsored GlobalStar Collaborative Study.

[44] Jongkind V, Yeung K, *et al.* Juxtarenal aortic aneurysm repair. *J. Vasc. Surg.* 2010 Sept; 29(3) 760–767.

[45] Landry G, Lau I, Liem T, Mitchell E, Moneta G.. Open abdominal aortic aneurysm repair in the endovascular era: Effect of clamp site on outcomes. Arch. Surg., 144 (9) Sep. 2009, 811–6.

2010 Census of Population and Housing data. For the FY 2013 wage index, to be effective October 1, 2012 and before the availability of OMB's new area delineations, we are proposing to use the same labor market areas that we used for the FY 2012 wage index (76 FR 51581).

C. Worksheet S–3 Wage Data for the FY 2013 Proposed Wage Index

The FY 2013 proposed wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2009 (the FY 2012 wage indices were based on data from cost reporting periods beginning during FY 2008).

1. Included Categories of Costs

The FY 2013 proposed wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty)
- Home office costs and hours
- Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315))
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2012, the proposed wage index for FY 2013 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2013 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397).

3. Use of Wage Index Data by Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index are also currently used to calculate wage indices applicable to other providers, such as SNFs, home health agencies (HHAs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indices for non-IPPS providers, other than for LTCHs. Such comments should be made in response to separate proposed rules for those providers.

D. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2013 proposed wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report for cost reporting periods beginning on or after October 1, 2008, and before October 1, 2009. For wage index purposes, we refer to cost reports during this period as the ''FY 2009 cost report,'' the ''FY 2009 wage data,'' or the ''FY 2009 data.'' Instructions for completing Worksheet S–3, Parts II and III are in the Provider Reimbursement Manual (PRM), Part II, sections 3605.2 and 3605.3. The data file used to construct the wage index includes FY 2009 data submitted to us as of March 2, 2011. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries/MACs to revise or verify data elements that result in specific edit failures. For the FY 2013 proposed wage index, we identified and excluded 32 providers with data that was too aberrant to include in the proposed wage index, although if data elements for some of these providers are corrected, we intend to include some of these providers in the FY 2013 final wage index. We instructed fiscal intermediaries/MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than April 11, 2012. We intend that all unresolved data elements will be resolved by the date the final rule is issued. The revised data will be reflected in the FY 2013 IPPS final rule.

In constructing the FY 2013 proposed wage index, we included the wage data for facilities that were IPPS hospitals in FY 2009, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397). For this proposed rule, we removed 7 hospitals that converted to CAH status between February 15, 2011, the cut-off date for CAH exclusion from the FY 2012 wage index, and February 14, 2012, the cut-off date for CAH exclusion from the FY 2013 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, the proposed FY 2013 wage index is calculated based on 3,443 hospitals.

For the FY 2013 proposed wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner we allotted such hospitals' data in the FY 2012 wage index (76 FR 51591). Table 2 containing the FY 2013 proposed wage index associated with this proposed rule (available on the CMS Web site) includes separate wage data for the campuses of four multicampus hospitals.

E. Method for Computing the Proposed FY 2013 Unadjusted Wage Index

The method used to compute the FY 2013 proposed wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012 final wage index without an occupational mix adjustment (76 FR 51591 through 51593).

As discussed in that final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2008, through April 15, 2010, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage for FY 2013. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2008	11/15/2008	1.03003
11/14/2008	12/15/2008	1.02786
12/14/2008	01/15/2009	1.02582
01/14/2009	02/15/2009	1.02386
02/14/2009	03/15/2009	1.02199
03/14/2009	04/15/2009	1.02014
04/14/2009	05/15/2009	1.01826
05/14/2009	06/15/2009	1.01635
06/14/2009	07/15/2009	1.01446
07/14/2009	08/15/2009	1.01263
08/14/2009	09/15/2009	1.01086
09/14/2009	10/15/2009	1.00910
10/14/2009	11/15/2009	1.00728
11/14/2009	12/15/2009	1.00539
12/14/2009	01/15/2010	1.00352
01/14/2010	02/15/2010	1.00172
02/14/2010	03/15/2010	1.00000
03/14/2010	04/15/2010	0.99830

For example, the midpoint of a cost reporting period beginning January 1, 2009, and ending December 31, 2009, is June 30, 2009. An adjustment factor of 1.01446 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as described above and in the FY 2012 IPPS–LTCH PPS final rule, the FY 2013 proposed national average hourly wage (unadjusted for occupational mix) is $37.4023. The proposed Puerto Rico overall average hourly wage (unadjusted for occupational mix) is $15.8467.

F. Proposed Occupational Mix Adjustment to the FY 2013 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the FY 2013 Proposed Occupational Mix Adjustment Based on the 2010 Occupational Mix Survey

As provided for under section 1886(d)(3)(E) of the Act, we collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program.

As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586), the FY 2013 proposed wage index is based on data collected on the new 2010 Medicare Wage Index Occupational Mix Survey (Form CMS–10079 (2010)). The survey is available on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage* and through the fiscal intermediaries/MACs. Hospitals were required to submit their completed 2010 surveys to their fiscal intermediaries/MACs by July 1, 2011. The preliminary, unaudited 2010 survey data was released in early October 2011, along with the FY 2009 Worksheet S–3 wage data, for the FY 2013 wage index review and correction process.

2. Calculation of the Proposed Occupational Mix Adjustment for FY 2013

For FY 2013, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012 wage index (76 FR 51582 through 51586). As a result of applying this methodology, the FY 2013 proposed occupational mix adjusted national average hourly wage is $37.3721. The FY 2013 proposed occupational mix adjusted Puerto Rico-specific average hourly wage is $15.8838.

Because the occupational mix adjustment is required by statute, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2013 wage index. For the FY 2010 survey, the response rate was 91.7 percent. In the FY 2013 proposed wage index established in this proposed rule, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586).

In the FY 2011 IPPS/LTCH PPS proposed and final rules (75 FR 23943 and 50167, respectively), we stated that, in order to gain a better understanding of why some hospitals are not submitting the occupational mix data, we will require hospitals that do not submit occupational mix data to provide an explanation for not complying. This requirement was effective beginning with the new 2010 occupational mix survey. We instructed fiscal intermediaries/MACs to begin gathering this information as part of the FY 2013 wage index desk review process. We will review these data for future analysis and consideration of potential penalties for noncompliant hospitals.

G. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2013 Occupational Mix Adjusted Wage Index

1. Analysis of the Occupational Mix Adjustment and the Occupational Mix Adjusted Wage Index

As discussed in section III.F. of this preamble, for FY 2013, we are proposing to apply the occupational mix adjustment to 100 percent of the proposed FY 2013 wage index. We calculated the proposed occupational mix adjustment using data from the 2010 occupational mix survey data, using the methodology described in the FY 2012 IPPS–LTCH PPS final rule (76 FR 51582 through 51586).

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2013 wage index results in a proposed national average hourly wage of $37.3721 and a proposed Puerto-Rico specific average hourly wage of $15.8838. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2009 Worksheet S–3, Parts II and III, cost report data for use in calculating the proposed FY 2013 wage index, we calculated the proposed FY 2013 wage index using the occupational mix survey data from 3,443 hospitals. Using the Worksheet S–3, Parts II and III, cost report data of 3,443 hospitals and occupational mix survey data from 3,157 hospitals represents a 91.7 percent survey response rate. The proposed FY 2013 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN	37.362735568
National LPN and Surgical Technician	21.762566488
National Nurse Aide, Orderly, and Attendant	15.312800678
National Medical Assistant	17.240367808
National Nurse Category	31.807020884

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $31.807020884. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2010 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 43.34 percent, and the national percentage of hospital employees in the all other occupations category is 56.66 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 27.03 percent in one CBSA, to a high of 59.70 percent in another CBSA.

We also compared the FY 2013 wage data adjusted for occupational mix from the 2010 survey to the FY 2013 wage data adjusted for occupational mix from the 2007–2008 survey. This analysis illustrates the effect on area wage indices of using the 2010 survey data compared to the 2007–2008 survey data; that is, it shows whether hospitals' wage indices are increasing or decreasing under the current survey data as compared to the prior survey data. Our analysis shows that the FY 2013 wage index values for 190 (48.6 percent) urban areas and 18 (37.5 percent) rural areas will increase. Fifty (12.8 percent) urban areas will increase by 1 percent or more, and no urban areas will increase by 5 percent or more. Three (6.3 percent) rural areas will increase by 1 percent or more, and no rural areas will increase by 5 percent or more. However, the wage index values for 197 (50.4 percent) urban areas and 30 (62.5 percent) rural areas will decrease using the 2010 data. Sixty-four (16.4 percent) urban areas will decrease by 1 percent or more, and no urban areas will decrease by 5 percent or more. Three (6.3 percent) rural areas will decrease by 1 percent or more, and no rural areas will decrease by 5 percent or more. The largest positive impacts using the 2010 data compared to the 2007–2008 data are 4.37 percent for an urban area and 3.24 percent for a rural area. The largest negative impacts are 4.86 percent for an urban area and 2.28 percent for a rural area. Four urban areas and no rural areas will be unaffected. These results indicate that the wage indices of more CBSAs overall (51.7 percent) will be decreasing due to application of the 2010 occupational mix survey data as compared to the 2007–2008 survey data to the wage index. Further, a larger percentage of urban areas (48.6 percent) will benefit from the 2010 occupational mix survey as compared to the 2007–2008 survey than will rural areas (37.5 percent).

We compared the proposed FY 2013 occupational mix adjusted wage indices for each CBSA to the proposed unadjusted wage indices for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the proposed wage index values for 207 (52.9 percent) urban areas and 32 (66.7 percent) rural areas would increase. One hundred seventeen (29.9 percent) urban areas would increase by 1 percent or more, and 3 (0.77 percent) urban areas would increase by 5 percent or more. Fourteen (29.2 percent) rural areas would increase by 1 percent or more, and no rural areas would increase by 5 percent or more. However, the wage index values for 184 (47.1 percent) urban areas and 15 (31.3 percent) rural areas would decrease. Eighty-five (21.7 percent) urban areas would decrease by 1 percent or more, and one urban area would decrease by 5 percent or more (0.26 percent). Seven (14.6 percent) rural areas would decrease by 1 percent or more, and no rural areas would decrease by 5 percent or more. The largest positive impacts are 6.71 percent for an urban area and 3.10 percent for a rural area. The largest negative impacts are 5.22 percent for an urban area and 3.10 percent for a rural area. No urban areas are unaffected, but one rural area is unaffected. These results indicate that a larger percentage of rural areas (66.7 percent) would benefit from the occupational mix adjustment than do urban areas (52.9 percent). While these results are more positive overall for rural areas than under the previous occupational mix adjustment that used survey data from 2007–2008, approximately one-third (31.3 percent) of rural CBSAs would still experience a decrease in their wage indices as a result of the occupational mix adjustment.

2. Application of the Rural, Imputed, and Frontier Floors

a. Rural Floor

Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. In the FY 2013 proposed wage index associated with this proposed rule and available on the CMS Web site, 393 hospitals are receiving an increase in their FY 2013 proposed wage index due to the application of the rural floor.

b. Imputed Floor and Proposal for an Alternative, Temporary Methodology for Computing the Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109), we adopted the ''imputed floor'' policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy three times, with the latest extension being set to expire on September 30, 2013 (we refer readers to the discussion in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593)). There are currently two all-urban States, New Jersey and Rhode Island, that have a range of wage indices assigned to hospitals in the State, including through reclassification or redesignation (we refer readers to discussions of geographic reclassifications and redesignations in section III.H. of this preamble). However, as we explain below, the current method for computing the imputed floor benefits only New Jersey, and not Rhode Island.

The current methodology for computing the imputed floor is contained in our regulations at 42 CFR 412.64(h)(4). In computing the imputed floor, we calculate the ratio of the lowest-to-highest CBSA wage index for each all-urban State (that is, New Jersey and Rhode Island) as well as the average of the ratios of lowest-to-highest CBSA wage indices of those all-urban States. We compare the State's own ratio to the average ratio and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which establishes the imputed floor for the State. Rhode Island has only one CBSA (Providence-New Bedford-Fall River, RI–MA); therefore, Rhode Island's own ratio equals 1.0, and its imputed floor is equal to its original CBSA wage index value. Conversely, New Jersey has 10 CBSAs. As the average ratio of New Jersey and Rhode Island is higher than New Jersey's own ratio, the current methodology provides a benefit for New Jersey.

For the FY 2013 wage index, the final year of the extension of the imputed floor policy under § 412.64(h)(4), we are proposing an alternative, temporary methodology for computing the imputed floor wage index to address the concern that the current imputed floor methodology guarantees a benefit for one all-urban State with multiple wage indices but cannot benefit the other. This proposed alternative methodology for calculating the imputed floor would be established using empirical data from the application of the rural floor policy for FY 2013. Under this proposal, we would first determine the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with this proposed rule and available on the CMS Web site includes the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values would then be increased by this factor, the result of which would establish the State's alternative imputed floor. We are proposing to amend § 412.64(h)(4) to add new paragraphs (v)(A) and (B) to incorporate this proposed alternative methodology, and to make conforming references.

In addition, for the FY 2013 wage index, we are proposing no changes to the current imputed floor methodology at § 412.64(h)(4) and, therefore, no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we are proposing a second, alternative methodology that would be used in cases where an all-urban State has a range of wage indices assigned to its hospitals, but the State cannot benefit from the methodology in existing § 412.64(h)(4). We intend to further evaluate the need, applicability, and methodology for the imputed floor before the September 30, 2013 expiration of the imputed floor policy and address these issues in the FY 2014 proposed rule.

The proposed wage index and impact tables associated with this FY 2013 proposed rule that are available on the CMS Web site include the application of the imputed floor policy at § 412.64(h)(4) and a national budget neutrality adjustment for the imputed floor. There are 29 providers in New Jersey that would receive an increase in their FY 2013 proposed wage index due to the imputed floor policy. The proposed wage index and impact tables for this proposed rule do not reflect the application of the proposed second alternative methodology for computing the imputed floor, which we anticipate would benefit four hospitals in Rhode Island.

c. Frontier Floor

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000 (we refer readers to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160). Four States in the FY 2013 proposed wage index are being treated as frontier States: Montana, North Dakota, South Dakota, and Wyoming; 51 providers in these States are receiving the frontier floor value of 1.0000 in the FY 2013 proposed wage index associated with this proposed rule. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 proposed rural floor value of 1.0293 is greater and, therefore, is the State's proposed minimum wage index for FY 2013.

The areas affected by the rural, imputed, and frontier floor policies for the FY 2013 proposed wage index are identified in Table 4D associated with this proposed rule and available on the CMS Web site.

3. Proposed FY 2013 Wage Index Tables

The proposed wage index values for FY 2013 (except those for hospitals receiving wage index adjustments under section 1886(d)(13) of the Act), included in Tables 4A, 4B, 4C, and 4F, available on the CMS Web site, include the proposed occupational mix adjustment, geographic reclassification or redesignation as discussed in section III.H. of this preamble, and the application of the rural, imputed, and frontier State floors as discussed in section III.G.2. of this preamble.

Tables 3A and 3B, available on the CMS Web site, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2007, 2008, and 2009 cost reporting periods. Table 3A lists these data for urban areas, and Table 3B lists these data for rural areas. In addition, Table 2, which is available on the CMS Web site, includes the adjusted average hourly wage for each hospital from the FY 2007 and FY 2008 cost reporting periods, as well as the FY 2009 period used to calculate the proposed FY 2013 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period. The proposed average hourly wages in Tables 2, 3A, and 3B, which are available on the CMS Web site, include the proposed occupational mix adjustment. The proposed wage index values in Tables 4A, 4B, 4C, and 4D also

include the proposed national rural and imputed floor budget neutrality adjustment. The proposed wage index values in Table 2 also include the proposed outmigration adjustment for eligible hospitals.

H. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify 13 months prior to the start of the fiscal year for which reclassification is sought (generally by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion of the proximity requirements in the FY 2002 IPPS final rule (66 FR 39874 and 39875).) The general policies for reclassifications and redesignations that we are proposing for FY 2013, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). Also, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification pursuant to 42 CFR 412.103.

2. FY 2013 MGCRB Reclassifications

a. FY 2013 Reclassification Requirements and Approvals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2013 reclassification requests. Based on such reviews, there were 238 hospitals approved for wage index reclassifications by the MGCRB for FY 2013. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2013, hospitals reclassified during FY 2011 or FY 2012 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 277 hospitals approved for wage index reclassifications in FY 2011, and 255 hospitals approved for wage index reclassifications in FY 2012. Of all of the hospitals approved for reclassification for FY 2011, FY 2012, and FY 2013, based upon the review at the time of this proposed rule, 770 hospitals are in a reclassification status for FY 2013.

Under 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887) and the FY 2003 IPPS final rule (67 FR 50065). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2013 will be incorporated into the wage index values published in the FY 2013 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

b. Applications for Reclassifications for FY 2014

Applications for FY 2014 reclassifications are due to the MGCRB by September 4, 2012 (the first working day of September 2012). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2012, via the Internet on the CMS Web site at: *http://cms.hhs.gov/MGCRB/02_instructions_and_applications.asp*, or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

3. Redesignations of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B) of the Act requires us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA if certain criteria are met. Effective beginning FY 2005, we use OMB's 2000 CBSA standards and the Census 2000 data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties have been known as ''Lugar'' hospitals and the counties themselves are often referred to as ''Lugar'' counties. The FY 2013 chart with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

4. Reclassifications Under Section 1886(d)(8)(B) of the Act

As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Affected hospitals are permitted to compare the reclassified wage index for the labor market area in Table 4C associated with this proposed rule (available on the CMS Web site) into which they would be reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals may withdraw from an MGCRB reclassification within 45 days of the publication of this FY 2013 proposed rule. (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51598 through 51599) for the procedural rules and requirements for a hospital that is redesignated under section 1886(d)(8)(B) of the Act and seeking reclassification under the MGCRB, as well as our policy of measuring the urban area, exclusive of the Lugar County, for purposes of meeting proximity requirements.) We treat New England deemed counties in a manner consistent with how we treat Lugar counties. (We refer readers to FY 2008 IPPS final rule with comment period (72

FR 47337) for a discussion of this policy.)

5. Reclassifications Under Section 508 of Public Law 108–173

Section 508 of Public Law 108–173 allowed certain qualifying hospitals to receive wage index reclassifications and assignments that they otherwise would not have been eligible to receive under the law. Although section 508 originally was scheduled to expire after a 3-year period, Congress extended the provision several times, as well as certain special exceptions that would have otherwise expired. For a discussion of the original section 508 provision and its various extensions, we refer readers to the FY 2012 notice, CMS–1442–N, which went on public display at the Office of the Federal Register on April 19, 2012, and was published in the **Federal Register** on April 20, 2012. The most recent extension of the provision was included in section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96), which extends certain section 508 reclassifications and special exception wage indices for a 6-month period during FY 2012, from October 1, 2011 through March 31, 2012. As of the drafting of this proposed rule, section 508 reclassifications and certain special exceptions have not been extended for FY 2013.

6. Waiving Lugar Redesignation for the Out-Migration Adjustment

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.G. of this preamble.)

In addition, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within the requisite number of days from the publication of the proposed rule [47]) to automatically waive its urban status for the 3-year period for which its out-migration adjustment is effective. That is, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the adjustment. Thus, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule), that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) for a detailed discussion of the policy and process for waiving Lugar status for the out-migration adjustment.

I. Proposed FY 2013 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with the broad discretion granted to the Secretary under section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. The proposed FY 2013 out-migration adjustment is based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment (we refer readers to a full discussion of the adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602)). Table 4J, available via the Internet on the CMS Web site, lists the out-migration adjustments for the FY 2013 proposed wage index.

J. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data and occupational mix survey data files for the proposed FY 2013 wage index were made available on October 4, 2011, through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional public use file on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this new file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and the scheduling of the Hospital Open Door forums at the CMS Web site at: *http://www.cms.hhs.gov/OpenDoorForums/*.

In a memorandum dated September 29, 2011, we instructed all fiscal intermediaries/MACs to inform the IPPS hospitals they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the fiscal intermediaries/MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the October 4, 2011 wage and occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its fiscal intermediary/MAC by December 5, 2011. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage index data files on the Internet, through the September 29, 2011 memorandum referenced above.

In the September 29, 2011 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the CY 2010 occupational mix preliminary files posted to the CMS Web site in October, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete

[47] Hospitals generally have 45 days from publication of the proposed rule to request an out-migration adjustment in lieu of the section 1886(d)(8) deemed urban status.

documentation to its fiscal intermediary/MAC no later than December 5, 2011.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2012 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-December revision requests. The fiscal intermediaries/MACs also submitted the revised data to CMS by mid-February 2012. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 21, 2012. Hospitals had until March 5, 2012, to submit requests to the fiscal intermediaries/MACs for reconsideration of adjustments made by the fiscal intermediaries/MACs as a result of the desk review, and to correct errors due to CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal intermediaries/MACs were required to transmit any additional revisions resulting from the hospitals' reconsideration requests by April 11, 2012. The deadline for a hospital to request CMS intervention in cases where the hospital disagrees with the fiscal intermediary's (or, if applicable, the MAC's) policy interpretations was April 18, 2012.

Hospitals should examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available on the CMS Web site at: *http://www.cms.gov*. Table 2 contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2009 data used to construct the proposed FY 2013 wage index. We note that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by March 2012.

We will release the final wage index data public use files in early May 2012 on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp*. The May 2012 public use files are made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary/MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the fiscal intermediaries/MACs by April 11, 2012). If, after reviewing the May 2012 final public use files, a hospital believes that its wage or occupational mix data are incorrect due to a fiscal intermediary/MAC or CMS error in the entry or tabulation of the final data, the hospital should send a letter to both its fiscal intermediary/MAC and CMS that outlines why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). CMS and the fiscal intermediaries (or, if applicable, the MACs) must receive these requests no later than June 4, 2012.

Each request also must be sent to the fiscal intermediary/MAC. The fiscal intermediary/MAC will review requests upon receipt and contact CMS immediately to discuss any findings.

After the release of the May 2012 wage index data files, changes to the wage and occupational mix data will only be made in those very limited situations involving an error by the fiscal intermediary/MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the fiscal intermediary/MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries or the MACs on or before April 11, 2012.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 21, 2012 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the fiscal intermediary or the MAC or CMS during the wage index data correction process.

Verified corrections to the wage index data received timely by CMS and the fiscal intermediaries or the MACs (that is, by June 4, 2012) will be incorporated into the final wage index in the FY 2013 IPPS/LTCH PPS final rule, which will be effective October 1, 2012.

We created the processes described above to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2013 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the fiscal intermediary's (or, if applicable, the MAC's) decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision. (See *W. A. Foote Memorial Hospital* v. *Shalala,* No. 99–CV–75202–DT (E.D. Mich. 2001) and *Palisades General Hospital* v. *Thompson,* No. 99–1230 (D.D.C. 2003).) We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the fiscal intermediary's (or, if applicable, the MAC's) attention. Moreover, because hospitals have access to the final wage index data by early May 2012, they have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or the MAC or CMS before the development and publication of the final FY 2013 wage index by August 2012, and the implementation of the FY 2013 wage index on October 1, 2012. If hospitals avail themselves of the opportunities afforded to provide and make corrections to the wage and occupational mix data, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after June 4, 2012, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The fiscal intermediary or the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the June 4 deadline for making corrections to the wage data for the following fiscal year's wage index. This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the fiscal intermediaries or the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the

wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when: (1) The fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the fiscal intermediary (or, if applicable, the MAC) and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the June 4, 2012 deadline for the FY 2013 wage index); and (3) CMS agreed that the fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the June 4, 2012 deadline), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In other situations where our policies would allow midyear corrections, we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a judicial decision reverses a CMS denial of a hospital's wage index data revision request.

K. Labor-Related Share for the Proposed FY 2013 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: ''The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates * * *.'' We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this ''would result in lower payments to a hospital than would otherwise be made.'' However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate ''from time to time'' the proportion of hospitals' costs that are ''attributable to wages and wage-related costs.'' Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43856), we rebased and revised the hospital market basket for operating costs. We established a FY 2006-based IPPS hospital market basket to replace the FY 2002-based IPPS hospital market basket, effective October 1, 2009. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2010. We also recalculated a labor-related share of 68.8 percent, using the FY 2006-based IPPS market basket, for discharges occurring on or after October 1, 2009. In addition, we implemented this revised and rebased labor-related share in a budget neutral manner, but consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In this FY 2013 proposed rule, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to in the FY 2002-based IPPS market basket as labor-intensive).

Therefore, for FY 2013, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012. Tables 1A and 1B, which are published in section VI. of the Addendum to this proposed rule and available via the Internet, reflect this labor-related share. We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this employment ''would result in lower payments to a hospital than would otherwise be made.'' Therefore, for all IPPS hospitals whose wage indices are less than 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indices are greater than 1.0000, we are proposing to apply the wage index to a labor-related share of 68.8 percent of the national standardized amount.

For Puerto Rico hospitals, the national labor-related share will always be 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0. In this proposed rule, we are proposing to continue to use a labor-related share for the Puerto Rico-specific standardized amounts of 62.1 percent for discharges occurring on or after October 1, 2012. This Puerto Rico labor-related share of 62.1 percent was also adopted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43857) at the time the FY 2006-based hospital market basket was established, effective October 1, 2009. Consistent with our methodology for determining the national labor-related share, we added the Puerto Rico-specific relative weights for wages and salaries, fringe benefits, contract labor, the labor-related portion of professional fees, administrative and business support services, and all other labor-related services (previously referred to

in the FY 2002-based IPPS market basket as labor-intensive) to determine the labor-related share. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. The labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related share of 62.1 percent or 62 percent, depending on which results in higher payments to the hospital. If the hospital has a Puerto Rico-specific wage index of greater than 1.0, we will set the hospital's rates using a labor-related share of 62.1 percent for the 25 percent portion of the hospital's payment determined by the Puerto Rico standardized amounts because this amount will result in higher payments. Conversely, a hospital with a Puerto Rico-specific wage index of less than 1.0 will be paid using the Puerto Rico-specific labor-related share of 62 percent of the Puerto Rico-specific rates because the lower labor-related share will result in higher payments. The Puerto Rico labor-related share of 62.1 percent for FY 2013 is reflected in Table 1C, which is published in section VI. of the Addendum to this proposed rule and available via the Internet.

IV. Other Decisions and Proposed Changes to the IPPS for Operating Costs and Graduate Medical Education (GME) Costs

A. Hospital Readmissions Reduction Program

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

Section 1886(q)(1) of the Act sets forth the methodology by which payments to ''applicable hospitals'' will be adjusted to account for excess readmissions. Pursuant to section 1886(q)(1) of the Act, payments for discharges from an ''applicable hospital'' will be an amount equal to the product of the ''base operating DRG payment amount'' and the adjustment factor for the hospital for the fiscal year. That is, ''base operating DRG payments'' are reduced by an adjustment factor that accounts for excess readmissions. Section 1886(q)(1) of the Act requires the Secretary to make payments for a discharge in an amount equal to the product of ''the base operating DRG payment amount'' and ''the adjustment factor'' for the hospital in a given fiscal year. Section 1886(q)(2) of the Act defines the base operating DRG payment amount as ''the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by * * * any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d).'' Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection(d) refer to outlier payments, IME payments, DSH payments, and payments for low-volume hospitals, respectively.

Furthermore, section 1886(q)(2)(B) of the Act specifies special rules for defining ''the payment amount that would otherwise be made under subsection (d)'' for certain hospitals. Specifically, section 1886(q)(2)(B) of the Act states that ''[i]n the case of a Medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital * * * the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).'' We are proposing policies to implement the statutory provisions related to the definition of ''base operating DRG payment amount'' in this proposed rule.

Section 1886(q)(3)(A) of the Act defines the ''adjustment factor'' for an applicable hospital for a fiscal year as equal to the greater of ''(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. It states that the ratio is ''equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions * * * and (ii) the aggregate payments for all discharges * * *.'' Section 1886(q)(3)(C) of the Act describes the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act sets forth the definitions of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' for an applicable hospital for the applicable period. The term ''aggregate payments for excess readmissions'' is defined in section 1886(q)(4)(A) of the Act as ''the sum, for applicable conditions * * * of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the ''Excess Readmission Ratio * * * for such hospital for such applicable period minus 1.'' The ''Excess Readmission Ratio'' is a hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the Excess Readmission Ratio as the ratio of ''risk-adjusted readmissions based on actual readmissions'' for an applicable hospital for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of ''applicable condition,'' ''expansion of applicable conditions,'' ''applicable hospital,'' ''applicable period,'' and ''readmission.'' The term ''applicable condition,'' which is addressed in detail in section IV.C.3.a. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666), is defined as a ''condition or procedure selected by the Secretary among conditions and procedures for which: (i) Readmissions * * * represent conditions or procedures that are high volume or high expenditures * * * and (ii) measures of such readmissions * * * have been endorsed by the entity with a contract under section 1890(a) * * * and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).'' Section 1886(q)(5)(B) of the Act also requires the Secretary, beginning in FY 2015, ''to the extent practicable, [to] expand the applicable conditions beyond the 3 conditions for which measures have been endorsed * * * to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary.''

Section 1886(q)(5)(C) of the Act defines ''applicable hospital,'' that is, a hospital subject to the Hospital Readmissions Reduction Program, as a ''subsection (d) hospital or a hospital that is paid under section 1814(b)(3) [of the Act], as the case may be.'' The term ''applicable period,'' as defined under

section 1886(q)(5)(D) of the Act, ''means, with respect to a fiscal year, such period as the Secretary shall specify.'' As explained in the FY 2012 IPPS/LTCH PPS final rule, the ''applicable period'' is the period from which data are collected in order to calculate various ratios and adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the public reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for all hospital inpatients for ''specified hospitals'' in order to calculate the hospital-specific readmission rates for all hospital inpatients and to publicly report these readmission rates.

2. Overview

As we stated in the FY 2012 IPPS/LTCH PPS final rule, we intend to implement the requirements of the Hospital Readmissions Reduction Program in the FY 2012, FY 2013, and future IPPS/LTCH PPS rulemaking cycles.

As explained above, the payment adjustment factor set forth in section 1886(q) of the Act does not apply to discharges until FY 2013. Therefore, we elected to implement the Hospital Readmissions Reduction Program over a 2-year period, beginning in FY 2012. In the FY 2012 IPPS/LTCH PPS final rule, we addressed the issues of the selection of readmission measures and the calculation of the excess readmission ratio, which will be used, in part, to calculate the readmission adjustment factor. Specifically, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed portions of section 1886(q) of the Act related to the following provisions:

- Selection of applicable conditions;
- Definition of ''readmission;''
- Measures for the applicable conditions chosen for readmission;
- Methodology for calculating the excess readmission ratio; and
- Definition of ''applicable period.''

With respect to the topics of ''measures for readmission'' for the applicable conditions, and ''methodology for calculating the excess readmission ratio,'' we specifically addressed the following:

- Index hospitalizations;
- Risk adjustment;
- Risk standardized readmission rate;
- Data sources; and
- Exclusion of certain readmissions.

We are providing below a summary of the provisions of section 1886(q) of the Act that were finalized in the FY 2012 IPPS/LTCH PPS final rule.

Applicable conditions: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666), we finalized the applicable conditions for the FY 2013 Hospital Readmissions Reduction Program as heart failure (HF), acute myocardial infarction (AMI), and pneumonia (PN). Section 1886(q)(5)(A) of the Act requires that the ''applicable conditions'' be conditions or procedures for which readmissions are ''high volume or high expenditure'' and that ''measures of such readmissions'' have been endorsed by the entity with a contract under section 1890(a) of the Act (currently National Quality Forum (NQF)) and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge. In this proposed rule, we are proposing to codify this definition of ''applicable conditions'' in the regulations we are proposing at 42 CFR 412.152.

In the FY 2012 IPPS/LTCH PPS final rule, we discussed how each of the finalized ''applicable conditions'' for FY 2013 meets these statutory requirements. We noted that section 1886(q)(5)(B) of the Act allows for the Secretary to expand the conditions for the Hospital Readmissions Reduction Program starting in FY 2015.

Readmission: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666), we finalized a definition of ''readmission'' as occurring when a patient is discharged from an applicable hospital and then admitted to the same or another acute care hospital, that is, another applicable hospital, within a specified time period (30 days) from the date of discharge from the initial index hospitalization. In this proposed rule, we are proposing to codify this definition of ''readmission'' under the regulations we are proposing at 42 CFR 412.152. As also discussed in the FY 2012 IPPS/LTCH PPS final rule, only one readmission during the 30 days following the discharge from the initial hospitalization will count as a readmission for purposes of calculating the ratios set forth in section 1886(q)(3) of the Act. For any given patient, none of the subsequent readmissions he or she experiences within 30 days after discharge would be counted as a new ''index'' admission (that is, an admission evaluated for a subsequent readmission).

Measures for applicable conditions: As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666 and 51667), we will use three NQF-endorsed, hospital risk-standardized readmission measures for FY 2013, which are currently in the Hospital IQR Program: Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure (NQF #0505); Heart Failure 30–Day Risk Standardized Readmission Measure (NQF #0330); and Pneumonia 30-day Risk Standardized Readmission Measure (NQF #0506). The measures, as endorsed by the NQF, include the 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions.

As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673), we will use the risk-standardized readmission ratio of the NQF-endorsed readmission measures as the excess readmission ratio. The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (that is, patients with the same risk factors for readmission such as age and comorbidities), the ratio will be less than 1.0. If a hospital performs worse than average, the ratio will be greater than 1.0.

Measure methodology: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51668 through 51669), we finalized the methodology of the measures and are summarizing it briefly below.

Index hospitalizations included in the measure calculation: We finalized the definition of ''index hospital'' consistent with the NQF-endorsed definition. The measures define an index hospitalization as a hospitalization evaluated in the measure for a possible readmission within 30 days after discharge (that is, a hospitalization included in the measure calculation). The measures exclude as index hospitalizations any hospitalization for patients with an in-hospital death, without at least 30 days post-discharge enrollment in Medicare fee-for-service (FFS), discharged against medical advice, and under the age of 65.

Risk adjustment: The three measures, as endorsed by the NQF and finalized in the FY 2012 IPPS/LTCH PPS final rule, adjust for key factors that are clinically relevant and have strong relationships with the outcome (for example, patient demographic factors, patient coexisting medical conditions, and indicators of patient frailty). Under the current NQF-endorsed methodology, these covariates are obtained from Medicare claims extending 12 months prior to, and including, the index admission. This risk-adjustment approach adjusts for differences in the clinical status of the patient at the time of the index admission as well as for demographic variables. A complete list of the

variables used for risk adjustment and the clinical and statistical process for selecting the variables for each NQF-endorsed measure, as proposed, is available at the Web site: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841*.

Data sources: The finalized measures use Medicare inpatient claims data for Medicare FFS patients 65 years and older to identify index hospitalizations and readmissions. For risk adjustment, the measures use Part A and Part B claims for the 12 months prior to the index hospitalization as well as index hospitalization claims.

Exclusion of certain readmissions: The NQF-endorsed measures of readmissions finalized in the FY 2012 IPPS/LTCH PPS final rule include exclusions of readmissions consistent with the statutory requirement that all measures exclude certain readmissions that are unrelated to the prior discharge, such as transfers to other acute care facilities and planned readmissions.

Minimum number of discharges for applicable conditions: Section 1886(q)(4)(C)(ii) of the Act allows the Secretary discretion to determine the minimum number of discharges for the applicable condition. We finalized a policy in the FY 2012 IPPS/LTCH PPS final rule that the minimum number of discharges for applicable conditions is 25 for each condition for the FY 2013 Hospital Readmissions Reduction Program.

Applicable period: Under 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year. In the FY 2012 IPPS/LTCH PPS final rule, we finalized our policy to use 3 years worth of claims data to calculate the proposed readmission measures. Specifically, we finalized the policy to use claims data from July 1, 2008, to June 30, 2011, to calculate the excess readmission ratios and to calculate the FY 2013 Hospital Readmissions Reduction Program payment adjustment. As discussed in section IV.A.3.d. of this preamble, for the purpose of this proposed rule, the excess readmission ratios used to model our proposed methodology to calculate the Hospital Readmissions Reduction Program payment adjustment will be based on the 3-year time period of July 1, 2007 to June 30, 2010. For the final rule, we intend to use excess readmission ratios based on the applicable period of July 1, 2008 to June 30, 2011, as finalized in the FY 2012 IPPS/LTCH PPS final rule. In this proposed rule, we are proposing to codify the definition of ''applicable period'' under the regulations we are proposing at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmission ratios and adjustments for the fiscal year.

Excess Readmission Ratio calculation: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673 through 51676), we finalized the excess readmission ratio pursuant to section 1886(q)(4)(C) of the Act. We established the excess readmission ratio as the risk-standardized readmission ratio from the NQF-endorsed measures. The ratio is calculated using hierarchical logistic regression. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore variation in hospital patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal difference in quality. The method produces an adjusted actual (or ''predicted'') number in the numerator and an ''expected'' number in the denominator. The expected calculation is similar to that for logistic regression—it is the sum of all patients' expected probabilities of readmission, given their risk factors and the risk of readmission at an average hospital.

For each hospital, the numerator of the ratio used in the NQF-endorsed methodology (actual adjusted readmissions) is calculated by estimating the probability of readmission for each patient at that hospital and summing up over all the hospital's patients to get the actual adjusted number of readmissions for that hospital. Mathematically, the numerator equation can be expressed as:

Numerator: Adjusted Actual Readmissions

Step 1:

Calculate each patient's predicted probability of readmission = $\frac{1}{1 + e^{-Z_a}}$

Z_a = hospital-specific effect + $X\beta$

intercept + risk-adjustment coefficients

Step 2:

To get the numerator result, add all patients' predicted probabilities of readmission

The denominator of the risk-standardized ratio (excess readmission ratio) under this NQF-endorsed methodology sums the probability of readmission for each patient at an average hospital. This can be expressed mathematically as:

Denominator: Expected Readmissions

Step 1:

Calculate each patient's expected probability of readmission $= \frac{1}{1 + e^{-Ze}}$

$Z_e = X\beta$

intercept + risk-adjustment coefficients

Step 2:

To get the denominator result, add all patients' expected probabilities of readmission

Thus, the ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (excess readmission ratio) greater than one. In summary, in the FY 2012 IPPS/LTCH PPS final rule, we defined the ''excess readmission ratio'' as the risk-standardized readmission ratio of the NQF-endorsed readmission measures. More in-depth detail surrounding the methodology of excess readmission ratio calculation can be accessed on the Web site at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

In this proposed rule, we are proposing to codify the definition of ''excess readmission ratio'' under the regulations we are proposing at 42 CFR 412.152 as a hospital-specific ratio for each applicable condition for an applicable period, which is the ratio (but not less than 1.0) of (1) risk-adjusted readmissions based on actual readmissions for an applicable hospital for each applicable condition to (2) the risk-adjusted expected readmissions for the applicable hospital for the applicable condition.

3. FY 2013 Proposed Policies for the Hospital Readmissions Reduction Program

a. Overview

In this proposed rule, we are addressing the provisions in section 1886(q) of the Act that are related to the Hospital Readmissions Reduction Program payment adjustment, as well as any other provisions in section 1886(q) of the Act that were not addressed in the FY 2012 IPPS/LTCH PPS final rule that are effective for discharges beginning on or after October 1, 2012. Specifically, in this proposed rule, we are addressing section 1886(q) of the Act related to the following provisions:

- Base operating DRG payment amount, including policies for SCHs and MDHs and hospitals paid under section 1814(b) of the Act;
- Adjustment factor (both the ratio and floor adjustment factor);
- Aggregate payments for excess readmissions and aggregate payments for all discharges;
- Applicable hospital;
- Limitations on review;
- Reporting of hospital-specific information, including the process for hospitals to review and submit corrections.

We are proposing to establish a new Subpart I under 42 CFR Part 412 to incorporate the rules relating to the payment adjustments under the Hospital Readmissions Reduction Program.

b. Proposals Regarding Base Operating DRG Payment Amount, Including Special Rules for SCHs and MDHs and Hospitals Paid Under Section 1814 of the Act

(1) Proposed Definition of Base Operating DRG Payment Amount (Proposed § 412.152)

Under the Hospital Readmissions Reduction Program at section 1886(q) of the Act, payments for discharges from an ''applicable hospital'' will be an amount equal to the product of the ''base operating DRG payment amount'' and an ''adjustment factor'' that accounts for excess readmissions for the hospital for the fiscal year, for discharges beginning on or after October 1, 2012. Specifically, section 1886(q)(1) of the Act requires the Secretary to make payments for a discharge in an amount equal to the product of ''the base operating DRG payment amount'' and ''the adjustment factor'' for the hospital in a given fiscal year. The ''base operating DRG payment amount'' is defined under section 1886(q)(2) of the Act as ''the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by * * * any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d).'' Paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d) [of section 1886 of the Act] refer to outlier payments, indirect medical education (IME) payments, disproportionate share (DSH) payments, and low-volume hospital payments, respectively.

In general, ''the payment amount that would otherwise be made under subsection (d) * * * for a discharge'' (that is, the discharge payment amount made under section 1886(d) of the Act) determined without consideration of the adjustments to payments made under the Hospital VBP Program (section 1886(o) of the Act) or under the Hospital Readmissions Reduction Program (section 1886(q) of the Act) is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment (COLA) for hospitals located in Alaska and Hawaii), which is often

referred to as the ''wage-adjusted DRG operating payment.'' This payment amount may then be further adjusted if the hospital qualifies for an IME adjustment (under section 1886(d)(5)(B) of the Act), a DSH payment adjustment (under section 1886(d)(5)(F) of the Act), and/or a low-volume payment adjustment (under section 1886(d)(12) of the Act), or if the discharge qualifies for an outlier payment (under section 1886(d)(5)(A) of the Act). Furthermore, certain discharges may qualify for an additional payment for new medical services or technologies under section 1886(d)(5)(K) of the Act (often referred to as a ''new technology add-on payment'').

Consistent with section 1886(q)(2) of the Act, under the regulations we are proposing at 42 CFR 412.152, we would define the ''base operating DRG payment amount'' under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payments. As required by the statute, the proposed definition of ''base operating DRG payment amount'' does not include adjustments or add-on payments for IME, DSH, outliers and low-volume hospitals provided for under sections 1886(d)(5)(B), (d)(5)(F), (d)(5)(A), and (d)(12) of the Act, respectively. Section 1886(q)(2) of the Act does not exclude new technology payments made under section 1886(d)(5)(K) of the Act; therefore, any payments made under section 1886(d)(5)(K) of the Act are included in the proposed definition of ''base operating DRG payment amount.'' In addition, under the regulations we are proposing at 42 CFR 412.152, we are proposing to define ''wage-adjusted DRG operating payment'' as the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii). We are proposing that, under § 412.154(b)(1), to account for excess readmissions, an applicable hospital's base operating DRG payment amount is adjusted for each discharge occurring during the fiscal year. The payment adjustment for each discharge is determined by subtracting the product of the base operating DRG payment amount for such discharge by the hospital's admission payment adjustment factor for the fiscal year from the base operating DRG payment amount for such discharge.

Under this proposal, consistent with section 1886(q)(2)(B)(i) of the Act and proposed § 412.154(b)(2), for SCHs that receive payments based on their hospital-specific payment rate, we also are proposing to exclude the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate from the definition of ''base operating DRG payment amount.'' We note that, under the Hospital Readmissions Reduction Program at section 1886(q) of the Act, the proposed definition of ''base operating DRG payment amount'' would be used to calculate both the ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' under sections 1886(q)(4)(A) and (B) of the Act, which would then be used to determine the readmission adjustment factor that accounts for excess readmissions under section 1886(q)(3) of the Act (as discussed in greater detail in section IV.A.3.c. of this preamble), and would also be used to determine which payment amounts will be adjusted to account for excess readmissions. (We note that, as discussed in section IV.G. of this preamble, under current law, the MDH program expires at the end of FY 2012 (that is, the MDH program is currently only applicable to discharges occurring before October 1, 2012). Therefore, due to the expiration of the MDH program beginning with FY 2013, we are not including MDHs in the discussion of our proposals regarding the base operating DRG payment amount in this proposed rule.)

(2) Proposal on Special Rules for Certain Hospitals: Hospitals Paid Under Section 1814(b)(3) of the Act (Proposed § 412.154(d))

Although the definition of ''applicable hospital'' under section 1886(q)(5)(C) of the Act includes hospitals paid under section 1814(b)(3) of the Act (that is, certain Maryland hospitals), section 1886(q)(2)(B)(ii) of the Act allows the Secretary to exempt such hospitals from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings established by Congress for the program as applied to ''subsection (d) hospitals.'' Accordingly, a program established by the State of Maryland that could serve to exempt the State from the Hospital Readmissions Reduction program would focus on those ''applicable'' Maryland hospitals operating under the ''waiver'' provided by section 1814(b)(3) of the Act, that is, those hospitals that would otherwise have been paid by Medicare under the IPPS, absent the provision.

In this proposed rule, we are proposing to establish criteria for evaluation of an annual report to CMS to determine whether Maryland should be exempted from the program each year. Accordingly, we would evaluate a report submitted by the State of Maryland documenting how its program that is described below meets those criteria. Based on the information in the report, we would determine whether or not Maryland's readmission program meets our criteria to be exempt from the Hospital Readmissions Reduction Program for FY 2013. We note that our proposed criteria to evaluate Maryland's program is for FY 2013, the first year of the program, and our evaluation criteria may change through notice-and-comment rulemaking as the Hospital Readmissions Reduction Program evolves. We are proposing to codify this requirement at § 412.154(d) of the regulations.

Based on preliminary discussions with the State, we understand that, effective July 1, 2011, Maryland has established the Admission-Readmission Revenue (ARR) Program. The State has described its program as a voluntary program for acute care hospitals, of which 30 out of the 46 acute care hospitals in the State are currently enrolled. Under the program, the State pays hospitals under a case-mix adjusted bundled payment per episode of care, where the episode of care is defined as the initial admission and any subsequent readmissions to the same hospital or linked hospital system that occur within 30 days of the original discharge. According to the State, an initial admission with no readmissions provides the hospital with the same weight as an initial admission with multiple readmissions. Therefore, hospitals receive a financial reward for decreased readmissions (as determined through the case mix adjusted, episode of care weights). Unlike the Hospital Readmissions Reduction Program under section 1886(q) of the Act, which is currently based on measures for three conditions (HF, AMI, and PN) for the Medicare FFS population and only adjusts the IPPS operating payments, Maryland's program applies to all conditions for all patients. In addition, while the Hospital Readmissions Reduction Program considers a readmission to be a subsequent admission to either the original acute care hospital from where the patient was initially discharged or an admission to another acute care hospital, currently Maryland only tracks readmissions to the same acute care hospital (or linked

hospital system) from which the patient was originally discharged. The State has noted that, under its ARR program, the readmission rates for the hospitals participating in the ARR program for the first quarter of its fiscal year compared to the first quarter of its previous fiscal year decreased from 9.86 percent to 8.96 percent.

We are proposing to evaluate Maryland's ARR program based on whether the State can demonstrate that cost savings under its program achieve or exceed the savings to the Medicare program due to the Hospital Readmissions Reduction Program under section 1886(q) of the Act. We also are proposing to evaluate whether Maryland's program can demonstrate similar results in reducing unnecessary readmissions among hospitals in the State, as described in more detail below. With specific regard to Maryland's demonstration of cost savings, we are proposing to evaluate whether Maryland's ARR program can demonstrate savings to the Medicare program that are at least similar to those expected under the Hospital Readmissions Reduction Program. As discussed later in this proposed rule, we estimate that, under the Hospital Readmissions Reduction Program, for FY 2013, Medicare IPPS operating payments will decrease by approximately $300 million (or 0.3 percent) of total Medicare IPPS operating payments. Maryland has indicated that it believes it can achieve comparable savings because it intends to reduce the rate update factor for all hospitals by 0.3 percent, regardless of a hospital's performance on readmissions.

In addition, we plan to propose in future rulemaking to evaluate whether Maryland's ARR program can meet or exceed health outcomes that we expect to improve under the Hospital Readmissions Reduction Program. Because the Hospital Readmissions Reduction Program is not effective until October 1, 2012, we do not yet have measured health outcomes against which we can evaluate Maryland's ARR program. However, we intend to have outcomes data in the future with which to evaluate Maryland's ARR program. We anticipate that, under the Hospital Readmissions Reduction Program, hospitals will experience a reduction in unnecessary readmissions. Therefore, in future rulemaking, we intend to propose to evaluate whether Maryland's ARR program can demonstrate similar decreases in potential preventable readmissions among hospitals in the State. Furthermore, we are proposing that the State's annual report and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually in accordance with the statute and as proposed at § 412.154(d)(2).

Based on preliminary information provided by Maryland, the State believes that its program can meet our evaluation criteria and demonstrate that its program achieves or surpasses the measured results in terms of health outcomes and cost savings. We are reviewing whether the Maryland's ARR program, which currently cannot monitor readmissions to other hospitals and a financial reward for hospitals that reduce within-hospital readmissions and provides a 0.3 percent reduction to the annual rate update to account for comparable savings to the Hospital Readmissions Reduction Program, meets the criteria to exempt Maryland hospitals from the Hospital Readmissions Reduction Program. We welcome public comments on whether the Maryland ARR program meets the requirements for exemption from the Hospital Readmissions Reduction Program set forth in section 1886(q)(2)(B)(ii) of the Act.

For the purposes of modeling the impacts of this proposal in this proposed rule, we have modeled under the assumption that Maryland hospitals will not have Hospital Readmission Reduction Program adjustment factors applied to them. Although the adjustment factors do not apply to these hospitals under our models, Maryland hospitals have excess readmission ratios, consistent with the definition of excess readmission ratio. Any readmission to a Maryland hospital from a subsection(d) hospital in another State is still considered a readmission for purposes of the original hospital in another State. This is consistent with the definition of readmissions in section 1886(q)(5)(E) of the Act, which includes admissions to the same or another ''applicable hospital.'' As discussed above, we interpret the definition of ''applicable hospital'' under section 1886(q)(5)(C) of the Act includes both subsection (d) hospitals and hospitals paid under section 1814(b)(3) of the Act that would, absent the provisions of section 1814(b)(3) of the Act, be paid under subsection (d).

c. Proposals Regarding Adjustment Factor (Both the Ratio and Floor Adjustment Factor) (Proposed § 412.154(c))

Section 1886(q)(3)(A) of the Act defines the ''adjustment factor'' for an applicable hospital for a fiscal year as equal to the greater of ''(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act in turn describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is ''equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions * * *; and (ii) the aggregate payments for all discharges. * * *'' We are proposing to codify the calculation of this ratio at § 412.154(c)(1) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years. We are proposing to codify the floor adjustment factor at § 412.154(c)(2) of the regulations.

For FY 2013, under proposed § 412.154(c), we are proposing that an applicable hospital would receive an adjustment factor that is either the greater of the ratio described in section IV.A.3.d. of this preamble or a floor adjustment factor of 0.99. We are proposing that the ratio would be rounded to the fourth decimal place, consistent with the calculation of other IPPS payment adjustments such as the wage index, DSH adjustment, and the IME adjustment. In other words, a hospital included in this program can have an adjustment factor that is between 1.0 and 0.9900 for FY 2013. Consistent with section 1886(q)(3) of the Act, under proposed § 412.154(c), we are proposing that, for FY 2013, the hospital will receive an adjustment factor under the Hospital Readmissions Reduction Program that is the greater of the ratio or the floor of 0.99. Consistent with this proposal, under the regulations we are proposing at 42 CFR 412.152, we are proposing to define the ''floor adjustment factor'' as the value that the readmissions adjustment factor cannot be less than for a given fiscal year. As noted above, the floor adjustment factor is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

d. Proposals Regarding Aggregate Payments for Excess Readmissions and Aggregate Payments for All Discharges (Proposed § 412.152)

As discussed earlier, section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is ''equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions * * *; and (ii) the aggregate payments for all discharges * * *.'' In this section, we set forth

proposals to define aggregate payments for excess readmissions and aggregate payments for all discharges, as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges).

Section 1886(q)(4) of the Act sets forth the definitions of ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' for an applicable hospital for the applicable period. The term ''aggregate payments for excess readmissions'' is defined in section 1886(q)(4)(A) of the Act as ''for a hospital for an applicable period, the sum, for applicable conditions * * * of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the 'Excess Readmission Ratio' * * * for such hospital for such applicable period minus 1.'' We are proposing to include this definition of ''aggregate payments for excess readmissions'' under the regulations we are proposing at 42 CFR 412.152.

The ''excess readmission ratio'' is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmission ratio as the ratio of ''risk-adjusted readmissions based on actual readmissions'' for an applicable hospital for each applicable condition, to the ''risk-adjusted expected readmissions'' for the applicable hospital for the applicable condition. The methodology for the calculation of the excess readmission ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). ''Aggregate payments for excess readmissions'' is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The term ''aggregate payments for all discharges'' is defined at section 1886(q)(4)(B) of the Act as ''for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.'' ''Aggregate payments for all discharges'' is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. We are proposing to include this definition of ''aggregate payments for all discharges'' under the regulations we are proposing at § 412.152.

As discussed above, when calculating the numerator (aggregate payments for excess readmission), CMS determines the base operating DRG for the applicable period. ''Aggregate payments for excess readmissions'' (the numerator) is defined as ''the sum, for applicable conditions * * * of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the 'Excess Readmission Ratio' * * * for such hospital for such applicable period minus 1.''

We discussed above our proposed definition of ''base operating DRG payment amount.'' When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we are proposing to use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) to calculate the excess readmission ratio. We are proposing to use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking in order to determine IPPS rates. For FY 2013, we are proposing to use data from MedPAR claims with discharge dates that are on or after July 1, 2008, and no later than June 30, 2011, the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule. We are proposing to use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files for the final rules, as described in greater detail below). These are the same MedPAR files that are used in the annual IPPS rulemaking for each Federal fiscal year.

For the purposes of this proposed rule, for FY 2013, we are proposing to use the March 2009 update of the FY 2008 MedPAR file to identify claims within FY 2008 with discharges dates that are on or after July 1, 2008, the March 2010 update of the FY 2009 MedPAR file to identify claims within FY 2009, the March 2011 update of the FY 2010 MedPAR file to identify claims within FY 2010, and the December 2011 update of the FY 2011 MedPAR file to identify claims within FY 2011 with discharge dates no later than June 30, 2011. However, for the FY 2013 IPPS/LTCH PPS final rule, we plan to use the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2011, as these would be the most recently available FY 2011 claims data used for FY 2013 rulemaking. These MedPAR data files are used each year in other areas of the IPPS, including calculating the IPPS relative weights, budget neutrality factors, outlier thresholds, and the standardized amount. Accordingly, we believe it is appropriate to use these same data files for the purpose of calculating the readmission adjustment factors. The FY 2008 through FY 2011 MedPAR data files can be purchased from CMS. These files allow the public to verify the readmission adjustment factors. Interested individuals may order these files through the Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on the MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and further detailed instructions for how to order the data sets. Persons placing an order must send the following: a Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for $3,655 to:

Mailing address if using the U.S. Postal Service: Centers for Medicare and Medicaid Services, RDDC Account, Accounting Division, P.O Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail: Centers for Medicare and Medicaid Services, OFM/Division of Accounting RDDC, Mailstop C#–07–11, 7500 Security Boulevard, Baltimore, MD 21244–1850.

We note that, in this proposed rule, we are proposing to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2008, and no later than June 30, 2011, which is the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule. However, in this proposed rule, for the purposes of modeling, we are using excess readmission ratios based on an older performance period of July 1, 2007 to June 30, 2010. For the final rule, we intend to use both the excess readmission ratios and MedPAR claims data to calculate aggregate payments for excess readmissions and aggregate payments for all discharges based on the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule (July 1, 2008 to June 30, 2011).

In order to identify the admissions for each condition for an individual hospital for calculating the aggregate payments for excess readmissions, we are proposing to identify each applicable condition using the same ICD–9–CM codes used to identify applicable conditions to calculate the excess readmission ratios. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51669), in our discussion of the methodology of the readmissions measures, we stated that we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period. The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are listed in the *2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmission Measures.* They also are posted on the Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > methodologies.

In order to identify the applicable conditions to calculate the aggregate payments for excess readmissions, we are proposing to identify the claim as an applicable condition if the ICD–9–CM code for that condition is listed as the principal diagnosis on the claim, consistent with the methodology to identify conditions to calculate the excess readmission ratio. Furthermore, we are proposing to only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Part C, Medicare Advantage, would not be included in this calculation), consistent with the methodology to calculate excess readmission ratios based on readmissions for Medicare FFS patients. The tables below list the ICD–9–CM codes we are proposing to use to identify each applicable condition to calculate the aggregate payments for excess readmissions under this proposal. These ICD–9–CM codes will also be used to identify the applicable conditions to calculate the excess readmission ratios, consistent with our policy finalized in the FY 2012 IPPS/LTCH PPS final rule.

ICD–9–CM CODES TO IDENTIFY PNEUMONIA CASES

ICD–9–CM Code	Description of code
480.0	Pneumonia due to adenovirus.
480.1	Pneumonia due to respiratory syncytial virus.
480.2	Pneumonia due to parainfluenza virus.
480.3	Pneumonia due to SARS-associated coronavirus.
480.8	Viral pneumonia: pneumonia due to other virus not elsewhere classified.
480.9	Viral pneumonia unspecified.
481	Pneumococcal pneumonia [streptococcus pneumoniae pneumonia].
482.0	Pneumonia due to klebsiella pneumoniae.
482.1	Pneumonia due to pseudomonas.
482.2	Pneumonia due to hemophilus influenzae [h. influenzae].
482.30	Pneumonia due to streptococcus unspecified.
482.31	Pneumonia due to streptococcus group a.
482.32	Pneumonia due to streptococcus group b.
482.39	Pneumonia due to other streptococcus.
482.40	Pneumonia due to staphylococcus unspecified.
482.41	Pneumonia due to staphylococcus aureus.
482.42	Methicillin Resistant Pneumonia due to Staphylococcus Aureus.
482.49	Other staphylococcus pneumonia.
482.81	Pneumonia due to anaerobes.
482.82	Pneumonia due to escherichia coli [e.coli].
482.83	Pneumonia due to other gram-negative bacteria.
482.84	Pneumonia due to legionnaires' disease.
482.89	Pneumonia due to other specified bacteria.
482.9	Bacterial pneumonia unspecified.
483.0	Pneumonia due to mycoplasma pneumoniae.
483.1	Pneumonia due to chlamydia.
483.8	Pneumonia due to other specified organism.
485	Bronchopneumonia organism unspecified.
486	Pneumonia organism unspecified.
487.0	Influenza with pneumonia.
488.11	Influenza due to identified novel H1N1 influenza virus with pneumonia.

ICD–9–CM CODES TO IDENTIFY HEART FAILURE CASES

ICD–9–CM Code	Code description
402.01	Hypertensive heart disease, malignant, with heart failure.
402.11	Hypertensive heart disease, benign, with heart failure.
402.91	Hypertensive heart disease, unspecified, with heart failure.
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease.
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified failure and chronic kidney disease stage V or end stage renal disease.

ICD–9–CM CODES TO IDENTIFY HEART FAILURE CASES—Continued

ICD–9–CM Code	Code description
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease.
428.xx	Heart Failure.

ICD–9–CM CODES TO IDENTIFY ACUTE MYOCARDIAL INFARCTION CASES

ICD–9–CM Code	Description of Code
410.00	AMI (anterolateral wall)—episode of care unspecified.
410.01	AMI (anterolateral wall)—initial episode of care.
410.10	AMI (other anterior wall)—episode of care unspecified.
410.11	AMI (other anterior wall)—initial episode of care.
410.20	AMI (inferolateral wall)—episode of care unspecified.
410.21	AMI (inferolateral wall)—initial episode of care.
410.30	AMI (inferoposterior wall)—episode of care unspecified.
410.31	AMI (inferoposterior wall)—initial episode of care.
410.40	AMI (other inferior wall)—episode of care unspecified.
410.41	AMI (other inferior wall)—initial episode of care.
410.50	AMI (other lateral wall)—episode of care unspecified.
410.51	AMI (other lateral wall)—initial episode of care.
410.60	AMI (true posterior wall)—episode of care unspecified.
410.61	AMI (true posterior wall)—initial episode of care.
410.70	AMI (subendocardial)—episode of care unspecified.
410.71	AMI (subendocardial)—initial episode of care.
410.80	AMI (other specified site)—episode of care unspecified.
410.81	AMI (other specified site)—initial episode of care.
410.90	AMI (unspecified site)—episode of care unspecified.
410.91	AMI (unspecified site)—initial episode of care.

Section 1886(q)(2) of the Act defines the base operating DRG payment amount as ''the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o) [the Hospital VBP Program]) for a discharge if this subsection did not apply; reduced by * * * any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d).'' Paragraphs (d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of section 1886 refer to outlier payments, IME payments, DSH payments, and payments for low-volume hospitals, respectively.

As discussed earlier in section IV.A.3.b.(1) of this preamble, we are proposing to define ''base operating DRG payment amount'' under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any new technology add-on payments. Thus, in order to calculate the base operating DRG payment amount for such condition for such hospital, we are proposing to identify the base operating DRG payment amount for such conditions based on the payment amounts in the MedPAR files on the claims identified to meet those conditions based on their ICD–9–CM code.

As discussed in section IV.A.3.b. of this preamble, applicable hospitals in the Hospital Readmissions Reduction Program include SCHs and current MDHs (whose status is set to expire at the end of FY 2012), as these hospitals meet the definition of subsection (d) hospitals. SCHs are paid in the interim (prior to cost report settlement) on a claim-by-claim basis at the amount that is the higher of the payment based on the hospital-specific rate or the IPPS Federal rate based on the standardized amount. At cost report settlement, the fiscal intermediary or MAC determines whether the hospital would receive higher IPPS payments in the aggregate using the hospital-specific rate (on all claims) or the Federal rate (on all claims). MDHs are paid the sum of the Federal payment amount plus 75 percent of the amount by which their hospital-specific rate exceeds the Federal payment amount. Although MDH status is to expire beginning in FY 2013, because we are using historical data to determine the base operating DRG payments to calculate adjustment factor, the payments reflected on claims for current MDHs may be based on the hospital-specific rate. For SCHs and current MDHs, we are proposing to model their base operating DRG payment amount as they would have been paid under the Federal standardized amount, rather than using the information on the claim (which may represent a payment either made under the hospital-specific rate or the Federal rate) so that their payments are consistent with our proposed definition of base operating DRG payment. As such, the payment difference between the payment made under the hospital-specific rate and the payment made under the Federal rate is not included in the base operating DRG amount to determine the readmission adjustment factor; that is, it is neither included in the numerator of the aggregate dollars for excess readmissions nor in the denominator of the aggregate dollars for all discharges.

As discussed earlier, we are proposing to use data from the MedPAR files that contain claims from the 3-year applicable period of July 1, 2008, to June 30, 2011, for FY 2013 to calculate aggregate payments for excess readmissions (the numerator of the ratio). To calculate aggregate payments for excess readmissions, we are proposing to calculate the base operating DRG payment amounts for all the claims in the 3-year applicable period that list each applicable

condition as the principal diagnosis (as described above). Once we have calculated the base operating DRG payment amounts for all the claims that list each condition as the principal diagnosis, we are proposing to add up the base operating DRG payment amounts by each condition, resulting in three summed amounts, one amount for each of the three applicable conditions. We then are proposing to multiply each amount for each condition by their respective excess readmission ratio minus 1. The methodology for the calculation of the excess readmission ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). We are proposing that the excess readmission ratios for each condition used to calculate the numerator of this ratio are excess readmission ratios that have gone through the proposed review and correction process described later in this proposed rule. Each product in this computation represents the payment for excess readmissions for that condition. We are proposing to then sum the resulting products, which represent a hospital's proposed ''aggregate payments for excess readmissions'' (the numerator of the ratio).

If a hospital has an excess readmission ratio that is greater than 1 for a condition, that hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. As such, it will have aggregate payments for excess readmissions. If a hospital has an excess readmission ratio that is less than (or equal) to one, that hospital has performed better (or on average), with respect to readmissions for that applicable condition, than an average hospital with similar patients. As such, that hospital would not be considered to have ''aggregate payments'' for excess readmissions, and its payments would not be reduced under section 1886(q) of the Act. As described in section 1886(q)(4)(C) of the Act, and finalized in the FY 2012 IPPS/LTCH PPS final rule, the excess readmission ratio used cannot be less than 1 because the hospital will not have aggregate payments for excess readmissions and will not be subject to a readmission payment adjustment, as the hospital will have performed better than average. Because this calculation is performed separately for the three conditions, a hospital's excess readmission ratio must be less than or equal to 1 on each measure to avoid aggregate payments for excess readmissions.

Section 1886(q)(4)(B) of the Act defines ''aggregate payments for all discharges'' (the denominator of the ratio) as ''for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.'' We are proposing to use the same MedPAR files to calculate the denominator as we are proposing to use to calculate the numerator, for the 3-year applicable period of July 1, 2008 to June 30, 2011, for FY 2013. We are proposing to calculate base operating DRG payments in the same manner as we calculate base operating DRG payments for the numerator. We are proposing to sum the base operating DRG payment amounts for all Medicare FFS claims for such hospital during the 3-year applicable period. We also are proposing that we would model base operating DRG payment amount for SCHs and current MDHs as they would have been paid under the Federal standardized amount, rather than using the information on the claim (as described above).

We are proposing that the ratio described in section 1886(q)(3)(B) of the Act is 1 minus the ratio of the numerator and denominator described above. In addition, we are proposing that the readmission adjustment for an applicable hospital is the higher of this ratio under section 1886(q)(3)(B) of the Act or the floor of 0.99 for FY 2013. Consistent with this proposal, under the regulations we are proposing at 42 CFR 412.152, we are proposing to define ''readmissions adjustment factor'' as equal to the greater of: (i) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges or (ii) the floor adjustment factor.

For this proposed rule, for the purpose of modeling the proposed aggregate payments for excess readmissions and the proposed readmissions adjustment factors, we are using excess readmission ratios for the applicable hospitals from the 3-year period of July 1, 2007 to June 30, 2010, because the underlying data from this period have already been available to the public on the Hospital Compare Web site (as of July 2011). The data from the 3-year applicable period for FY 2013 of July 1, 2008 to June 30, 2011, have not been through the review and correct process required by section 1886(q)(6) of the Act (as discussed below). For the final rule, we intend to use excess readmission ratios based on discharges for the finalized applicable period of July 1, 2008 to June 30, 2011, to calculate the aggregate payments for excess readmissions and, ultimately, to calculate the readmission adjustment factors. Applicable hospitals will have had the opportunity to review and correct these data before they are made public under our proposal set forth below regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act.

Formulas To Calculate the Readmission Adjustment Factor

Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI × (Excess Readmission Ratio for AMI–1)] + [sum of base operating DRG payments for HF × (Excess Readmission Ratio for HF–1)] + [sum of base operating DRG payments for PN × (Excess Readmission Ratio for PN–1)].

Aggregate payments for all discharges = sum of base operating DRG payments for all discharges.

Ratio = 1 − (Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Readmissions Adjustment Factor for FY 2013 is the higher of the ratio or 0.99.

*Based on claims data from July 1, 2008 to June 30, 2011 for FY 2013.

During the FY 2012 IPPS rulemaking cycle, we received public comments expressing concern that hospitals that treat a larger proportion of patients of lower socioeconomic circumstances may have higher readmission rates and could be unfairly penalized under the Hospital Readmissions Reduction Program. The table below shows, based on the excess readmission ratios and the proposed methodology to calculate the readmissions adjustment factor discussed in this proposed rule, the estimated distribution of the readmission adjustment factors among hospitals ranked by their DSH patient percentage (DPP). The DPP is used as a proxy for low-income patients and is the sum of the hospital's Medicare fraction and Medicaid fraction. The Medicare fraction is computed by dividing the number of a hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days. The DPP is used to determine a hospital's Medicare DSH payment adjustment. Thus, hospitals with higher

percentages of Medicare patients entitled to SSI and higher percentages of Medicaid patients have higher DPPs. In the table, the hospitals are ranked by their estimated DPP and categorized into deciles. The table shows the number of hospitals within each decile that are subject to no proposed readmission payment adjustment, the −1 percent floor readmission payment adjustment, and a readmission payment adjustment that is less than the −1 percent floor. We are inviting public comment on this analysis.

DISTRIBUTION OF HOSPITALS READMISSION ADJUSTMENT FACTOR BY DSH PATIENT PERCENTAGE (DPP)

Decile	Number of hospitals	Payment adjustment of less than −1 percent	−1 Percent floor adjustment	No readmission adjustment factor
Lowest DPP	339	156	38	145
Second	339	164	57	118
Third	339	168	44	127
Fourth	339	170	48	121
Fifth	339	182	42	115
Sixth	339	171	43	125
Seventh	339	187	44	108
Eighth	339	182	43	114
Ninth	339	179	58	102
Highest DPP	342	185	61	96
Total	3,393	1,744	478	1,171

In addition, we have examined the estimated distribution of the proposed readmission adjustment factor based on the excess readmission ratios in this proposed rule (determined using the 2007–2010 data discussed above). The table below shows the number and percentage of hospitals ranked by the percent reduction received under the Hospital Readmissions Reduction Program. The table shows that about 71 percent of hospitals would receive either no adjustment or a readmission adjustment factor that would reduce their base operating DRG payments by less than 0.5 percent.

DISTRIBUTION OF READMISSION ADJUSTMENT FACTORS

Percent reduction	Number of hospitals	Percent of hospitals
No Adjustment	1,171	34.5
Up to −.09 Percent	347	10.2
−0.1 Percent to −0.19 Percent	280	8.3
−0.20 Percent to −0.29 Percent	228	6.7
−0.30 Percent to −0.39 Percent	196	5.8
−0.40 Percent to −0.49 Percent	180	5.3
−0.50 Percent to −0.59 Percent	129	3.8
−0.60 Percent to −0.69 Percent	118	3.5
−0.70 Percent to −0.79 Percent	110	3.2
−0.80 Percent to −0.89 Percent	77	2.3
−0.90 Percent to −0.99 Percent	76	2.2
−1.0 Percent	481	14.2
Total	3,393	100.0

e. Proposals Regarding Applicable Hospitals

An ''applicable hospital,'' is defined at section 1886(q)(5)(C) of the Act as (1) ''a subsection(d) hospital or (2) a hospital that is paid under section 1814(b)(3).'' Specifically, hospitals subject to the Hospital Readmissions Reduction Program are hospitals paid under the IPPS and hospitals paid under the authority of section 1814(b)(3) of the Act. We are interpreting this reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' specified by section 1814(b)(3) of the Act, would have been paid under the IPPS. A subsection (d) hospital is defined in section 1886(d)(1)(B) of the Act, in part, as a ''hospital located in one of the fifty States or the District of Columbia.'' The term subsection (d) hospital does not include hospitals located in the Territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a ''subsection(d) Puerto Rico hospital'' as a hospital that is located in Puerto Rico and that ''would be a subsection(d) hospital * * * if it were located in one of the 50 States.'' Therefore, Puerto Rico hospitals are not considered applicable hospitals under the Hospital Readmissions Reduction Program. Indian Health Services hospitals enrolled as a Medicare provider meet the definition of a subsection (d) hospital and, therefore, are considered an applicable hospital under the Hospital Readmissions Reduction Program, even if they are not paid under the IPPS. In addition, hospitals that are SCHs and current MDHs, although they may be paid under a hospital-specific rate instead of under the Federal rate under the IPPS, are subsection (d) hospitals and, therefore, are included in the definition of an applicable hospital

under the Hospital Readmissions Reduction Program.

A subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, and IPFs, and, therefore, these hospitals are not considered ''applicable hospitals.'' CAHs are not ''applicable hospitals'' because they do not meet the definition of a ''subsection (d) hospital,'' as they are separately defined under section 1886(mm) of the Act and are paid under a reasonable cost methodology under section 1814(l) of the Act. Consistent with the statute, therefore, we are proposing to define ''applicable hospital'' under the regulations at 42 CFR 412.152 to include both (1) subsection (d) hospitals, that is, hospitals paid under the IPPS and (2) hospitals in Maryland that are paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

The term ''applicable hospital'' is also referenced in the definition of readmission in section 1886(q)(5)(E) of the Act, which defines ''readmission'' as ''in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge.'' In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666), we finalized the definition of readmission as ''occurring when a patient is discharged from the applicable hospital and then is admitted to the same or another acute care hospital within a specified time period from the time of discharge from the index hospitalization.'' Furthermore, we finalized the time period specified for these readmission measures as 30 days. With our proposal to define an applicable hospital as a subsection (d) hospital or certain Maryland hospitals described above, we also are proposing to refine the definition of readmission to only include admissions and readmissions occurring from an applicable hospital (that is, a subsection (d) hospital or certain Maryland hospitals) to the same or another applicable hospital (again, a subsection (d) hospital or certain Maryland hospitals) (proposed § 412.152). Accordingly, excess readmission ratios calculated for the purpose of the Hospital Readmissions Reduction Program would include only admissions and readmissions to ''applicable hospitals.''

We note that because the Hospital Readmissions Reduction Program only includes admissions and readmissions to ''applicable hospitals'' to calculate the excess readmission ratios used under section 1886(q) of the Act, these excess readmission ratios will differ from the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program. The excess readmission ratios for the purpose of the Hospital IQR Program were determined based on admissions and readmissions to all hospitals, not just hospitals specified in sections 1886(d) and 1814(b)(3) of the Act. Therefore, as discussed above, the excess readmission ratios used in this proposed rule will use a subset of the claims used to calculate the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program and would be limited to admissions and readmissions to ''applicable hospitals'' and are based on the period of June 30, 2007 to July 1, 2010. In this proposed rule, we are using these excess readmission ratios, as they are based on the most recent data available and will allow the public to replicate our methodology to understand how the readmission adjustment factor is calculated. We believe that the differences between these proposed excess readmission ratios and those excess readmission ratios currently published on Hospital Compare under the Hospital IQR Program are minimal, and we believe that it is helpful for hospitals to see the impact of our proposed methodology to calculate the readmission adjustment using excess readmission ratios calculated under our methodology finalized in the FY 2012 IPPS/LTCH PPS final rule. For the final rule, we intend to use excess readmission ratios based on the applicable period of June 30, 2008 to July 1, 2011, as finalized in the FY 2012 IPPS/LTCH PPS final rule, and hospitals will have the opportunity to review and correct their data related to their excess readmission ratios prior to the publication of those excess readmission ratios.

We are specifically inviting public comment on our readmissions proposal, including our proposed definition of base operating DRG payment, our proposed methodology to calculate the readmission adjustment factor, the minimum number of cases, and our proposed definition of applicable hospital.

4. Limitations on Review (Proposed § 412.154(e))

Section 1886(q)(7) of the Act provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for any of the following:

- The determination of base operating DRG payment amounts.
- The methodology for determining the adjustment factor, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges, and applicable periods and applicable conditions.

We are proposing to include under proposed § 412.154(e) that the provisions listed above will not be subject to administrative or judicial review, consistent with section 1886(q)(7) of the Act. We note that section 1886(q)(6) of the Act requires that the Secretary ''make information available to the public regarding readmissions rates of each subsection (d) hospital under the [Hospital Readmissions Reduction Program]'' and also requires the Secretary to ''ensure that a subsection (d) hospital has the opportunity to review and submit corrections for, the information to be made public.'' Our proposal for reporting hospital-specific information, including a hospital's opportunity to review and submit corrections, consistent with section 1886(q)(7) of the Act, is discussed below.

5. Reporting Hospital-Specific Information, Including Opportunity To Review and Submit Corrections (Proposed § 412.154(f))

Section 1886(q)(6)(A) of the Act requires the Secretary to ''make information available to the public regarding readmissions rates of each subsection (d) hospital under the [Hospital Readmissions Reduction Program]''. Section 1886(q)(6)(B) of the Act also requires the Secretary to ''ensure that a subsection (d) hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital.'' In addition, section 1886(q)(6)(C) of the Act requires the Secretary to post the hospital-specific readmission information for each subsection (d) hospital on the Hospital Compare Web site in an easily understood format.

For purposes of the Hospital Readmissions Reduction Program for FY 2013, we will calculate excess readmission ratios for each of the three conditions, AMI, HF, and PN, using the previously finalized 3-year applicable period for the FY 2013 payment determination that spans from July 1, 2008 through June 30, 2011 (76 FR 51671), data sources, and the minimum number of discharges previously finalized in the FY 2012 IPPS/LTCH

PPS final rule for each applicable hospital (76 FR 51671 through 51672). We intend to make these excess readmission ratios available to the public, consistent with the requirements of section 1886(q)(6)(B) of the Act, as part of the FY 2013 rulemaking process, in addition to posting this information on the Hospital Compare Web site in a subsequent release.

In the FY 2012 IPPS/LTCH PPS final rule, we indicated that we would provide hospitals an opportunity to review and submit corrections using a process similar to what is currently used for posting results on Hospital Compare. We currently provide hospitals with the data elements necessary to verify the accuracy of their readmission rates for the Hospital IQR Program prior to posting their rates on Hospital Compare. Because we believe it is important to provide hospitals with relevant information available to hospitals for assessing payment impacts for purposes of the Hospital Readmissions Reduction Program, we plan to make the excess readmission ratios used for the Hospital Readmissions Reduction Program adjustment factor calculation available during the rulemaking cycle. As a result, the timeline and details of this process must accommodate the rulemaking timeline in addition to posting on Hospital Compare. We are proposing below the details regarding the process for hospitals to review and submit corrections to their excess readmission ratios prior to making this information available to the public in rulemaking and on Hospital Compare.

For FY 2013, we are proposing to deliver confidential reports and accompanying confidential discharge-level information to applicable hospitals as defined in section IV.A.2. of this preamble, which contain their excess readmission ratios for the three applicable conditions by June 20, 2012. These reports will be delivered in hospitals' secure QualityNet accounts. The information in the confidential reports and accompanying confidential discharge-level information would be calculated using the claims information we had available approximately 90 days after the last discharge date in the applicable period, which is when we would create the data extract for the calculations (we discuss this practice in more detail later).

The discharge-level information accompanying the excess readmission ratios would include the risk-factors for the discharges that factor into the calculation of the excess readmission ratio, as well as information about the readmissions associated with these discharges (such as dates, provider numbers, and diagnosis upon readmission). Our intent in providing this information is twofold: (1) To facilitate hospitals' verification of the excess readmission ratio calculations we provide during the review and correction period based upon the information CMS had available at the time our data extract was created; and (2) to facilitate hospitals' quality improvement efforts with respect to readmissions.

We are proposing to provide hospitals with a period of 30 days to review and submit corrections for their excess readmission ratios for the Hospital Readmissions Reduction Program. This 30-day period would begin the day hospitals' confidential reports and accompanying discharge-level information are posted to their QualityNet accounts. Based on previous experience with public reporting of measures under the Hospital IQR program, including the 30-day risk standardized readmission rates, we believe this 30-day period would allow enough time for hospitals to review their data and notify CMS of calculation errors, and for CMS to incorporate appropriate corrections to the excess readmission ratio calculations prior to the publication of the final rule, at which time the excess readmission ratios would be made available to the public in a table to be cited in the final rule and available via the Internet on the CMS Web site. During the review and correction period, hospitals should notify CMS of suspected errors in their excess readmission ratio calculations using the technical assistance contact information provided in their confidential reports.

The review and correction process we are proposing for the excess readmission ratios above would not allow hospitals to submit additional corrections related to the underlying claims data we used to calculate the ratios, or allow hospitals to add new claims to the data extract we used to calculate the ratios. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the calculations. For purposes of this program, we would calculate the excess readmission ratios using a static snapshot (data extract) taken at the conclusion of the 90 day period following the last date of discharge used in the applicable period. We recognize that under our current timely claims filing policy, hospitals have up to one year from the date of discharge to submit a claim to CMS. However, in using claims data to calculate measures for this program, we are proposing to create data extracts using claims in CMS' Common Working File (CWF) 90 days after the last discharge date in the applicable period which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2011, we would create the data extract on September 30, 2011, and use that data to calculate the ratios for that applicable period. Hospitals would then receive the excess readmission ratio calculations in their confidential reports and accompanying discharge-level information and they would have an opportunity to review and submit corrections for the calculations. As we stated above, hospitals would not be able to submit corrections to the underlying data that were extracted on September 30, 2011, and would also not be able to add claims to the data set. Therefore, we would consider hospitals' claims data to be complete for purposes of calculating the excess readmission ratios for the Hospital Readmissions Reduction Program at the conclusion of the 90-day period following the last date of discharge used in the applicable period.

We considered a number of factors in determining that a 90-day ''run-out'' period is appropriate for purposes of calculating claims based measures. First, we seek to provide timely quality data to hospitals for the purpose of quality improvement and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals based on their performance on measures as close in time to the performance period as possible. Finally, with respect to claims-based measures, we seek to have as complete a data set as possible, recognizing that hospitals have up to one year from the date of discharge to submit a claim under CMS' timely claims filing policy.

After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episode-based measures). We then need to generate and check the calculations, as well as program, populate, and deliver the confidential reports and accompanying data to be delivered to hospitals. We also are aware that hospitals would prefer to receive the calculations to be used for the Hospital Readmissions Reduction Program as soon as possible. Because several months lead time is necessary after acquiring the data to generate these claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to hospitals sooner than 18 to 24 months after the last discharge

date. We believe this would create an unacceptably long delay both for hospitals and for CMS to deliver timely calculations to hospitals for quality improvement and transparency, and ultimately timely readmission adjustment factors for purposes of this program. Therefore, we are proposing to extract the data needed to calculate the excess readmission ratios for this program 90 days after the last date of discharge for the applicable period so that we can balance the need to provide timely program information to hospitals with the need to calculate the claims-based measures using as complete a data set as possible.

During the 30-day review and correction process for the excess readmission ratios, if a subsection (d) hospital suspects that such discrepancies exist in the CMS application of the measures' methodology, it should notify CMS during the review and correction period using the technical support contacts provided in the hospital's confidential report. We would investigate the validity of each submitted correction and notify hospitals of the results. If we confirm that we made an error in creating the data extract or in calculating the excess readmission ratios, we would strive to correct the calculations, issue new confidential reports to subsection (d) hospitals, and then publicly report the corrected excess readmission ratios through the rulemaking process, and subsequently on Hospital Compare. However, if the errors take more time than anticipated to correct, not allowing for publication of the corrected ratios in the final rule, we would notify hospitals in the final rule that corrected ratios will be made available after the final rule through delivery of confidential reports followed by a second 30-day review and correction period, subsequent publication, and posting on Hospital Compare. In addition, we are proposing that any corrections to a hospital's excess readmission ratios would then be used to recalculate a hospital's ratio under section 1886(q)(4)(B) of the Act in order to determine the hospital's adjustment factor in accordance with section 1886(q)(3) of the Act.

We believe that this proposed process would fulfill the statutory requirements at section 1886(q)(6)(A), section 1886(q)(6)(B), and section 1886(q)(6)(C) of the Act. We further believe that the proposed process would allow hospitals to review and correct their excess readmission ratios. We note that, under the proposed process, hospitals would retain the ability to submit new claims and corrections to submitted claims for payment purposes in line with CMS' timely claims filing policies. However, we emphasize that the administrative claims data used to calculate the excess readmission ratios reflect the state of the claims at the time of extraction from CMS' Common Working File. Under the proposed process, a hospital's opportunity to submit corrections to the calculation of the excess readmission ratios ends at the conclusion of the review and correction period. We welcome public comments on the proposed review and corrections process for the Hospital Readmissions Reduction Program.

B. Sole Community Hospitals (SCHs) (§ 412.92)

1. Background

Section 1886(d)(5)(D)(iii) of the Act defines a sole community hospital (SCH) in part as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 463897).

2. Clarification of Regulations Regarding Duration of Classification (Proposed § 412.92(b)(3)(iv))

The regulations at § 412.92(b)(2) and (b)(3) address the effective dates of a classification as an SCH and the duration of this classification. Currently, a hospital's SCH classification status remains in effect without the need for reapproval unless there is a change in the circumstances under which the classification was approved. Section 412.92(b)(3) requires a hospital to notify the fiscal intermediary (or MAC) within 30 days of when a change occurs that could affect its classification as an SCH. Specifically, the regulations require an SCH to notify its fiscal intermediary or MAC if any of the following changes specified in § 412.92(b)(3)(ii) (A) through (E) occur:

- The opening of a new hospital in its service area.
- The opening of a new road between itself and a like provider within 35 miles.
- An increase in the number of beds to more than 50, if the hospital qualifies as an SCH under § 412.92(a)(1)(ii).
- Its geographic classification changes.
- Any changes to the driving conditions that result in a decrease in the amount of travel time between itself and a like provider if the hospital qualifies as an SCH under § 412.92(a)(3).

As discussed in the FY 2007 IPPS final rule (71 FR 48060), in the context of CMS becoming aware of several hospitals that had been paid based on SCH status, even after the original circumstances that led to the classification changed, CMS determined that an SCH's classification status would end 30 days after CMS notifies the SCH that it no longer meets the requirements to be classified as an SCH. However, if a hospital does not report when any one of the changes listed above occurs, CMS will cancel the hospital's SCH classification effective with the date that the hospital no longer met the criteria for SCH classification, subject to the reopening rules at 42 CFR 405.1885 (§ 412.92(a)(3)(i)).

For any change that is not listed under § 412.92(b)(3)(ii)(A) through (E) that affects an SCH's classification status, CMS requires a hospital to report that change to the fiscal intermediary or MAC only if it ''becomes aware'' of the change. If a hospital does not report a change, other than those listed under § 412.92(b)(3)(ii)(A) through (E), and it becomes known to CMS that the hospital had knowledge of that change, CMS will cancel the hospital's SCH classification effective with the date the hospital became aware of the event. Specifically, § 412.92(b)(3)(iii) states that ''a sole community hospital must report to the fiscal intermediary if it *becomes aware of any change* that would affect its classification as a sole community hospital beyond the events listed in paragraph (b)(3)(ii) of this section within 30 days of the event. If CMS determines that a sole community hospital has failed to comply with this requirement, CMS will cancel the hospital's classification as a sole community hospital effective with the date the hospital *became aware of the event* that resulted in the sole community hospital no longer meeting the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.'' (Emphasis added.)

It has come to our attention that the existing regulations only address a situation where an SCH no longer meets the requirements to be classified as an SCH. The existing language at § 412.92(b)(3)(iii) only refers to a hospital becoming aware of a ''change,'' because it deals specifically with a situation where a hospital was

appropriately classified as an SCH because it had previously met the requirements to become an SCH. However, the regulations do not explicitly address the situation where a hospital never met the requirements to be classified as an SCH, but was incorrectly classified as an SCH. We believe that the regulations need to be clarified to state explicitly our current authority that if a determination is subsequently made that, in fact, a hospital did not ever qualify as an SCH, the withdrawal of SCH status could be made retroactively to revoke the SCH status for the entire time period, consistent with the reopening rules at § 405.1885.

We continue to believe that any factor or information, not only a change or an event, that could affect a hospital's SCH classification status, must be reported by the SCH to its fiscal intermediary or MAC. Accordingly, we are proposing to revise the regulations by adding a new paragraph (b)(3)(iv) to § 412.92 to clarify our current authority that if CMS determines that the hospital was incorrectly classified as an SCH, SCH status could be cancelled retroactively, consistent with the provisions at § 405.1885.

3. Proposed Change to Effective Date of Classification for MDHs Applying for SCH Status Upon the Expiration of the MDH Program (Proposed § 412.92(b)(2)(v))

Under existing regulations at § 412.92(b)(2), a SCH's status is generally effective 30 days after CMS's written notification of approval. It has come to our attention that there may be a number of hospitals currently classified as MDHs under § 412.108 of the regulations that intend to apply for classification as SCHs upon the expiration of the MDH program provision on September 30, 2012. Those hospitals may be reluctant to apply for SCH classification status well before the expiration of their MDH status because they would prefer to maintain their MDH status for as long as possible. Conversely, if those hospitals were to wait to apply for SCH classification status after expiration of their MDH status, they could experience a financial hardship if there were a delay in the approval for SCH classification status. In order to facilitate a seamless transition for hospitals that are currently classified as MDHs and that will qualify as SCHs, we are proposing to add an exception to the effective dates of SCH classification by adding a new paragraph (v) under § 412.92(b)(2). We are proposing that, for any MDH that applies for SCH classification status at least 30 days prior to the expiration of the MDH program provision and requests that SCH classification status be effective with the expiration of the MDH program provision, and the MDH is approved for SCH classification status, the effective date of the hospital's classification as an SCH would be the day following the expiration date of the MDH program provision (that is, October 1, 2012). For example, Hospital A is an MDH that would like to maintain its MDH status for as long as possible and be classified as an SCH only after its MDH status expires. In order to seamlessly transition from MDH status to SCH status, Hospital A must apply for SCH status prior to September 1, 2012, and must request that, if approved, SCH classification status be effective with the expiration of the MDH program provision. If CMS determines that Hospital A qualifies for SCH status, the effective date of its SCH classification will be October 1, 2012.

C. Rural Referral Centers (RRCs): Annual Update to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs are also not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area where the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, ''[a]ny hospital classified as an RRC by the Secretary * * * for fiscal year 1991 shall be classified as such an RRC for fiscal year 1998 and each subsequent year.'' In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), CMS reinstated RRC status for all hospitals that lost the status due to triennial review or MGCRB reclassification. However, CMS did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum CMI and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513).) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2013 includes data from all urban hospitals nationwide, and the proposed regional values for FY 2013 are the median CMI values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2011 (October 1, 2010 through September 30, 2011), and include bills

posted to CMS' records through December 2011.

We are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2012, they must have a CMI value for FY 2011 that is at least—

- 1.5378; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the following table:

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.3085
2. Middle Atlantic (PA, NJ, NY)	1.3739
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4647
4. East North Central (IL, IN, MI, OH, WI)	1.4557
5. East South Central (AL, KY, MS, TN)	1.4025
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.4734
7. West South Central (AR, LA, OK, TX)	1.5861
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6132
9. Pacific (AK, CA, HI, OR, WA)	1.5156

The preceding numbers will be revised in the FY 2013 final rule to the extent required to reflect the updated FY 2011 MedPAR file, which will contain data from additional bills received through March 2012.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its fiscal intermediary or MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. We would normally propose to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2010 (that is, October 1, 2009 through September 30, 2010), which would normally be the latest cost report data available at the time of the development of this proposed rule. However, due to a transition in our data system, in lieu of a full year of FY 2010 cost report data, we needed to use a combination of FY 2009 and FY 2010 cost report data in order to create a full fiscal year of cost report data for this analysis. Due to CMS' transition to a new cost reporting form effective for cost reporting periods beginning on or after May 1, 2010, cost reports with fiscal year begin dates of May 1, 2010 through September 30, 2010 were not accessible on our system for analysis at the time of the development of this proposed rule. Therefore, in order to have a complete fiscal year of cost report data, we utilized FY 2009 cost report data for providers with fiscal years beginning on or after May 1, 2010 and by September 30, 2010, in addition to the FY 2010 cost report data for providers with fiscal years beginning on or after October 1, 2009 and before May 1, 2010.

Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2012, must have, as the number of discharges for its cost reporting period that began during FY 2010 (based on a combination of FY 2009 and FY 2010 cost report data as explained in the preceding paragraph), at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,159
2. Middle Atlantic (PA, NJ, NY)	11,448
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,728
4. East North Central (IL, IN, MI, OH, WI)	8,833
5. East South Central (AL, KY, MS, TN)	7,234
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	8,129
7. West South Central (AR, LA, OK, TX)	6,253
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,347
9. Pacific (AK, CA, HI, OR, WA)	8,745

These numbers will be revised in the FY 2013 final rule based on the latest available cost report data.

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges is the minimum criterion for all hospitals under this proposed rule.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2012, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2010 (based on a combination of FY 2009 and FY 2010 cost report data as explained earlier in this section).

D. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Expiration of the Affordable Care Act Provision for FYs 2011 and 2012

For FYs 2011 and 2012, the Affordable Care Act expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition. Beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. We discuss the proposed payment policies for FY 2013 in section IV.D.4. of this preamble.

2. Background

Section 1886(d)(12) of the Act, as added by section 406(a) of Public Law 108–173, provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective beginning FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is ''in addition to any payment calculated under this section.'' Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume add-on payment amount is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outliers. For SCHs and MDHs, the low-volume add-on payment amount is based on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

Section 1886(d)(12)(C)(i) of the Act defined a low-volume hospital as ''a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year.'' Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' means ''an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under Part A.'' Therefore, the term ''discharge'' refers to total discharges, regardless of payer (that is, not only Medicare discharges). Furthermore, under section 406(a) of Public Law 108–173, which initially added subparagraph (12) to section 1886(d) of the Act, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between ''the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.'' The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25 percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Therefore, the low-volume adjustment of an additional 25 percent continues to be provided for qualifying hospitals with less than 200 discharges.

3. Affordable Care Act Provisions for FYs 2011 and 2012

Sections 3125 and 10314 of the Affordable Care Act amended section 1886(d)(12) of the Act, modifying the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.

Sections 3125(3) and 10314(1) of the Affordable Care Act amended the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to make it easier for hospitals to qualify for the low-volume adjustment. Specifically, the provision specifies that, for FYs 2011 and 2012, a hospital qualifies as a low-volume hospital if it is ''more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year.'' In addition, section 1886(d)(12)(D) of the Act, as added by section 3125(4) and amended by section 10314 of the Affordable Care Act, provides that the payment adjustment (the applicable percentage increase) is to be determined ''using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year.''

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we revised our regulations at 42 CFR 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act. In addition to changing the regulations to conform them to the Affordable Care Act changes, we also defined, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(i). The definition of ''road miles'' continues to apply even after the Affordable Care Act provisions expire at the end of FY 2012. We also clarified the existing regulations to indicate that a hospital must continue to qualify as a low-volume hospital in order to receive the payment adjustment in that year; that is, it is not based on a one-time qualification. Furthermore, in that same final rule, we discussed the process for requesting and obtaining the low-volume hospital payment adjustment (75 FR 50240).

4. Proposed Payment Adjustment for FY 2013 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, effective for FY 2013 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. As discussed above, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act and as discussed above, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the

additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As described above, for FYs 2005 through 2010 and FY 2013 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 and 2012, CMS used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

For FY 2013 and for subsequent fiscal years, in addition to a discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion specified at § 412.101(b)(2)(i). Specifically, to meet the mileage criterion to qualify for the low-volume payment adjustment for FY 2013 and subsequent fiscal years, a hospital must be located more than 25 road miles from the nearest ''subsection (d) hospital.'' As mentioned above, we define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(i) (75 FR 30238 through 50275 and 50414).

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 30238 through 50275 and 50414), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. In order to qualify for the low-volume hospital payment adjustment, a hospital must provide to its fiscal intermediary or MAC sufficient evidence to document that it meets the discharge and distance requirements. The fiscal intermediary or MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment. The fiscal intermediary or MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria.

In order to receive a low-volume hospital payment adjustment under § 412.101, a hospital must notify and provide documentation to its fiscal intermediary or MAC that it meets the mileage criterion. The use of a Web-based mapping tool, such as MapQuest, as part of documenting that the hospital meets the mileage criterion for low-volume hospitals, is acceptable. The fiscal intermediary or MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance (in road miles, as defined in the regulations at § 412.101(a)) from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the fiscal intermediary or MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the low-volume mileage criterion. In addition, the fiscal intermediary or MAC will refer to the hospital's most recently submitted cost report to determine whether or not the hospital meets the discharge criterion. A hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year. As noted previously, a hospital must continue to meet the qualifying criterion at § 412.101(b)(2)(i) as a low-volume hospital (that is, the discharge criterion and the mileage criterion) in order to receive the payment adjustment in that year; that is, low-volume hospital status is not based on a ''one-time'' qualification.

In order to be a low-volume hospital in FY 2013 and subsequent fiscal years, in accordance with our previously established procedure, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the 25 percent low-volume add-on payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25 percent low-volume add-on payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination.

Specifically, for FY 2013, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2012, in order for the 25 percent low-volume add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2012 (through September 30, 2013). If a hospital's request for low-volume hospital status for FY 2013 is received after September 1, 2012, and if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25 percent low-volume add-on payment adjustment to determine the payment for the hospital's FY 2013 discharges, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination. For additional information on our established application process for the low-volume hospital payment adjustment, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 20574 through 20575), Transmittal 2060 (Change Request 7134; October 1, 2010), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), in addition to implementing the Affordable Care Act provisions affecting low-volume hospitals for FYs 2011 and 2012, we also implemented changes to the regulations at 42 CFR 412.101 to conform them to the statutory requirements to require that, beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment methodology will return to that which was in effect prior to the amendments made by the Affordable Care Act (that is, the low-volume hospital payment policy in effect for FYs 2005 through 2010). Therefore, no further revisions to the policy or to the

regulations at § 412.101 are required to conform them to the statutory requirement that the low-volume hospital policy in effect prior to the Affordable Care Act returns for FY 2013 and subsequent years.

E. Indirect Medical Education (IME) Payment Adjustment (§ 412.105)

1. IME Adjustment Factor for FY 2013

Under the IPPS, an additional payment amount is made to hospitals that have residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B) of the Act states that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2013, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2013 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

2. Clarification and Proposal Regarding Timely Filing Requirements Under Fee-for-Service Medicare

a. IME and Direct GME

The Balanced Budget Act of 1997 (Pub. L. 105–33) amended sections 1886(d) and 1886(h) of the Act by adding paragraphs (d)(11) and (h)(3)(D), respectively, to establish payment provisions for IME and direct GME costs to hospitals providing services to Medicare + Choice (now Medicare Advantage) enrollees. Sections 1886(d)(11) and 1886(h)(3)(D) of the Act specify that the Secretary shall provide for an ''additional payment amount'' for services furnished to individuals who are enrolled in a Medicare Advantage plan under Medicare Part C. To implement sections 1886(d)(11) and 1886(h)(3)(D) of the Act, we issued two final rules in the Federal Register that specifically addressed IME and direct GME payments to teaching hospitals for services provided to Medicare Advantage enrollees (the FY 1997 IPPS final rule (62 FR 46003) and the FY 1998 IPPS final rule (63 FR 26341)). Subsequent to the FY 1998 IPPS final rule, we (then HCFA) issued a Program Memorandum (PM), A–98–21, in July 1998, which outlined fiscal intermediary and standard system changes needed to process requests for IME and direct GME supplemental payments for services provided to Medicare Advantage enrollees. The PM explained that hospitals must submit their Medicare claims to the fiscal intermediary in UB–92 format in order for the standard system to process the claims so that hospitals may be paid the supplemental IME and direct GME payments for services provided to Medicare Advantage enrollees. It was always our intent that the claims filing requirements under 42 CFR Part 424, including the time limits at 42 CFR 424.44, fully applied to these claims submissions.

Existing § 424.44 of the regulations contains the time limits for filing all Medicare claims. In this proposed rule, we are clarifying again that the regulations governing time limits for filing claims at § 424.44 apply to claims submitted for IME and direct GME payments associated with services provided to Medicare Advantage enrollees. The process that was established by PM A–98–21 is within the same framework of the preexisting methodology for submitting claims under Medicare Part A. Therefore, because IME and direct GME payments for services provided to Medicare Advantage enrollees are also made under Medicare Part A, the same timely filing requirements that apply to other Part A claims for payments also apply to claims for IME and direct GME payments for services provided to Managed Advantage enrollees. In this proposed rule, we are clarifying once again that when hospitals submit claims for services provided to Medicare Advantage enrollees for additional IME and direct GME payments, the hospitals must comply with the regulations governing time limits for filing claims at § 424.44.

b. Nursing and Allied Health Education

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113) further amended section 1886 of the Act by adding subsection (l) to provide for additional payments to hospitals that operate nursing or allied health education programs and incur costs associated with services provided to Medicare+Choice (now Medicare Advantage) enrollees. Section 512 of the Benefits Improvement and Protection Act (BIPA) (Pub. L. 106–554) changed the formula for determining the additional payment amount paid to hospitals that operate nursing or allied health education programs and incur costs for services provided to Medicare+Choice (now Medicare Advantage) enrollees. We issued several PMs (Transmittals A–00–86 on November 22, 2000, and A–03–043 on May 23, 2003) to implement section 541 of the BBRA and section 512 of the BIPA. We also issued related Transmittal A–03–007 on February 3, 2003, and Transmittal A–03–045 on May 30, 2003, to instruct hospitals that operate a nursing or allied health education program and that qualify for additional payment related to services provided to Medicare Advantage enrollees to also submit those claims for processing as no-pay bills in the UB–92 format. These transmittals also instructed hospitals that are not paid under the IPPS, hospitals with rehabilitation and psychiatric units, and hospitals that operate approved nursing or allied health education programs (but may not have approved GME residency programs) to submit claims for services provided to Medicare Advantage enrollees to their fiscal intermediary in UB–92 format with specific condition codes present. In this proposed rule, we also are clarifying that the regulations governing the time limits for filing claims at § 424.44 also apply to claims submitted for nursing or allied health education program payments for services provided to Medicare Advantage enrollees.

c. Disproportionate Share Hospital (DSH) Payments

On July 20, 2007, we issued Change Request 5647 instructing applicable hospitals to submit no pay bills for their Medicare Advantage patients for FY 2007 forward in order for these days to be captured in the DSH calculation. Because we issued this request in the middle of FY 2007, we later believed it was appropriate to extend the deadline for submission of FY 2007 and FY 2008 no pay Medicare Advantage bills to August 31, 2010.

In this proposed rule, we are proposing to adopt a policy that hospitals that are required to submit no pay bills for services furnished on a prepaid capitation basis by a Medicare Advantage organization, or through cost settlement with either a health maintenance organization (HMO), a competitive medical plan (CMP), a health care prepayment plan (HCPP), or a demonstration, for the purpose of calculating the DSH patient percentage (DPP) must also do so within the time limits for filing claims specified at § 424.44. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50282), we

changed our methodology for calculating the SSI fraction of the DSH adjustment, in part, by using claims information that is updated 15 months after the close of each Federal fiscal year. We believed that allowing for a 15-month run-out period would more closely align the timing of the match process with the requirements for the timely submission of claims. As we stated in that final rule, hospitals may not have an incentive to submit no pay bills in as timely a manner as they would for fee-for-service claims. In order to ensure that no pay claims are properly incorporated into the DSH calculation, in this proposed rule, we are proposing to extend our rules regarding the timely submission of claims to no pay bills submitted for the purposes of calculating the DPP.

To clarify our existing policy for hospitals to file timely claims in order to receive supplemental IME, direct GME and/or nursing or allied health education payments for Medicare Advantage enrollees and to propose that hospitals that are required to submit no pay bills for the purpose of calculating the DPP must also follow the time limits for filing claims, we are proposing to revise the regulations at § 424.30 to reflect these requirements.

3. Other Related Proposed Policy Changes

In sections IV.F. and IV.I of this preamble, we present other proposed policy changes relating to determining labor and delivery bed counts for purposes of the DSH payment adjustment and relating to determining FTE resident caps for direct GME and IME payment purposes that would have an effect on the IME payment adjustment.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)

1. Background

For the most recent background discussion regarding the Medicare payment adjustment for subsection (d) hospitals that serve a significantly disproportionate number of low-income patients, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51681).

As we did in FY 2012 IPPS/LTCH PPS final rule, we are combining, under section IV.I.2. of this preamble, our discussion of proposed changes to the policies for counting beds in relation to the calculations for the IME adjustment at § 412.105(b) and the DSH payment adjustment at § 412.106(a)(1)(i) because the underlying concepts are similar, and we believe they should generally be interpreted in a consistent manner for both purposes.

2. Proposed Policy Change Relating to Treatment of Labor and Delivery Beds in the Calculation of the Medicare DSH Payment Adjustment and the IME Payment Adjustment

a. Background

Medicare's policy with respect to the treatment of labor and delivery services in the calculation of the Medicare DSH payment adjustment has undergone a number of changes over the years. (We refer readers to the background discussion regarding these policy changes in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43899 through 43901)). The most recent change in policy was adopted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule. Prior to FY 2010, our policy was to exclude from the count of inpatient days for purposes of the Medicare DSH calculation labor and delivery patient days associated with beds used for ancillary labor and delivery services when the patient did not occupy a routine bed prior to occupying an ancillary labor and delivery bed. This policy applied whether the hospital maintained separate labor and delivery rooms and postpartum rooms, or whether it maintained ''maternity suites'' in which labor, delivery, and postpartum services all occurred in the same bed. However, in the latter case, patient days were counted proportionally based on the proportion of (routine/ancillary) services furnished. (We refer readers to the example provided in the FY 2004 IPPS final rule (68 FR 45420) that describes how routine and ancillary days are allocated under this policy.)

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we revised our regulations to include in the DPP of the Medicare DSH adjustment all patient days associated with patients occupying labor and delivery beds once the patient has been admitted to the hospital as an inpatient, regardless of whether the patient days are associated with patients who occupied a routine bed prior to occupying an ancillary labor and delivery bed. Our rationale for adopting this change was that the costs associated with labor and delivery patient days are generally payable under the IPPS. Although we adopted this change with respect to labor and delivery *patient* days, we did not make a similar change to our policy for counting hospital beds.

b. Proposed Policy Change

As we recently stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51682), our policy for counting hospital beds is to include bed days available for IPPS-level acute care hospital services. In the FY 2004 IPPS final rule (68 FR 45417), we stated that beds in a particular unit would be considered available for IPPS-level acute care services if the services furnished in that unit were generally payable under the IPPS. Moreover, as stated above, our policy for counting patient days with respect to the Medicare DSH payment adjustment is to include patient days in units that provide services that are generally payable under the IPPS. Under our current policy, the services furnished to a labor and delivery patient are considered to be generally payable under the IPPS (74 FR 43900).

We recognize that, under our current policy, while the services furnished to a labor and delivery patient are considered to be generally payable under the IPPS, under § 412.105(b)(4), the bed where the services are furnished is not considered to be available for IPPS-level care.

Upon further examination of our existing policies, we believe that if a patient day is counted because the services furnished are generally payable under the IPPS, the bed in which the services were furnished should also be considered to be available for IPPS-level care. Accordingly, we believe it is appropriate to extend our current approach of including labor and delivery patient days in the DPP of the Medicare DSH payment adjustment to our rules for counting hospital beds for purposes of both the IME payment adjustment and the Medicare DSH payment adjustment. Specifically, because we have described labor and delivery patient days as being generally payable under the IPPS (74 FR 43900), we believe that the bed in which such services are furnished should also be considered to be available for IPPS-level care, and should be included in the count of beds available for IPPS-level acute care hospital services. The rules for counting hospital beds for purposes of the IME payment adjustment are codified in the IME regulations at § 412.105(b), which are cross-referenced in § 412.106(a)(1)(i) for purposes of determining the DSH payment adjustment.

In light of the similar policy rationales for determining patient days in the calculation of the Medicare DSH payment adjustment, and for determining bed days for both the Medicare DSH payment adjustment and

IME payment adjustment, we are proposing to include labor and delivery bed days in the count of available beds used in the IME and DSH calculations. Moreover, our proposal to treat labor and delivery patient days and bed days consistently is consistent with our approach with respect to the observation, swing-bed, and hospice days, which are excluded from both the patient day count and the available bed count. Accordingly, we are proposing to revise the regulations at § 412.105(b)(4) to remove from the list of currently excluded beds those beds associated with ''ancillary labor/delivery services.'' We are proposing that this regulation change would be effective for cost reporting periods beginning on or after October 1, 2012.

As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43900), our policy for counting labor and delivery patient days does not allow for the inclusion of days of labor and delivery patients who are not admitted to the hospital as inpatients. For example, if a woman presents at a hospital for labor and delivery services, but is determined by medical staff to be in false labor and is sent home without ever being admitted to the hospital as an inpatient, any days associated with such services furnished by the hospital would not be included in the DPP for purposes of the calculation of the Medicare DSH payment adjustment. For the same reason, days on which labor and delivery beds are used for such services also will be excluded from the count of available bed days.

G. Expiration of the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

Under current law, separate special payment protections are provided to a Medicare-dependent, small rural hospital (MDH) under the IPPS through the end of FY 2012. (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684.) The provisions for MDHs at section 1886(d)(5) of the Act expire at the end of FY 2012 (that is, with discharges occurring on September 30, 2012). As we discussed in the FY 2012 IPPS/LTCH PPS final rule, section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, as specified in section 5003(a) of Public Law 109–171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology from the end of FY 2011 to the end of FY 2012, by striking ''October 1, 2011'' and inserting ''October 1, 2012''. Section 3124(b) of the Affordable Care Act also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Section 3124(b)(2) of the Affordable Care Act also amended section 13501(e)(2) of OBRA 1993 to extend the provision permitting hospitals to decline reclassification as an MDH through FY 2012. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287 and 50414), we amended the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program through FY 2012. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), we did not make any additional changes to this regulatory text for FY 2012.

Because the MDH program is not authorized by statute beyond FY 2012, all hospitals that previously qualified for MDH status will no longer have MDH status and will be paid based on the Federal rate beginning in FY 2013. (We note that, in section IV.B.3. of this preamble, we are proposing to revise our SCH policies to allow MDHs to apply for SCH status and be paid as such under certain proposed conditions, following expiration of the MDH program.) For the FY 2013 impact of the expiration of the MDH program at the end of FY 2012, we refer readers to section I.G.2.j. of Appendix A to this proposed rule.

H. Proposed Changes in the Inpatient Hospital Update

1. FY 2013 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient operating costs by a factor called the ''applicable percentage increase.'' Prior to enactment of the Affordable Care Act, section 1886(b)(3)(B)(i)(XX) of the Act set the applicable percentage increase equal to the rate-of-increase in the hospital market basket for subsection (d) hospitals (hereafter referred to as ''IPPS hospitals'') in all areas, subject to the hospital submitting quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. For hospitals that did not provide these data, the update was equal to the market basket percentage increase less an additional 2.0 percentage points. The update for the hospital-specific rates for SCHs is set by section 1886(b)(3)(B)(iv) of the Act as discussed further below.

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2013 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is currently based on the first quarter 2012 forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2013 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. For FY 2013, we are not proposing any change in our methodology for calculating and applying the MFP adjustment. Similar to the market basket increase, we are using the most recent data available for this proposed rule to compute the MFP adjustment. Using the methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51690), based on the most recent data available for this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we based the proposed FY 2013 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI's) first quarter 2012 forecast of the FY 2006-based IPPS market basket rate-of-increase, which is estimated to be 3.0 percent. This proposed percentage increase, subject to the hospital submitting quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, is then reduced by the most recent estimate of the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2013) of 0.8 percent, which is calculated using the methodology described in the FY 2012 IPPS/LTCH

PPS final rule (76 FR 51690) and based on IGI's first quarter 2012 forecast. Following application of the MFP adjustment, the applicable percentage increase is then reduced by 0.1 percentage point, as required by section 1886(b)(3)(B)(xii) of the Act (as discussed in section I. of the Addendum to this proposed rule).

Consistent with current law, and based on IGI's first quarter 2012 forecast of the FY 2013 market basket increase, we are proposing an applicable percentage increase to the FY 2013 operating standardized amount of 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for economy-wide productivity (that is, the MFP adjustment) and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data under rules established in accordance with section 1886(b)(3)(B)(viii) of the Act in accordance with our rules. For hospitals that do not submit these quality data, we are proposing an applicable percentage increase to the operating standardized amount of 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.8 percentage point for the MFP adjustment, and less an additional adjustment of 0.1 percentage point). Lastly, we also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2013 market basket update and MFP adjustment in the final rule.

We are proposing to revise the existing regulations at 42 CFR 412.64(d)(1)(iv) to reflect the current law for the FY 2013 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to revise paragraph (d)(1)(iv) to reflect the applicable percentage increase to the FY 2013 operating standardized amount as the percentage increase in the market basket index less an MFP adjustment and less an additional reduction of 0.1 percentage point.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an update to the hospital-specific rates applicable to SCHs of 2.1 percent for hospitals that submit quality data or 0.1 percent for hospitals that fail to submit quality data. For FY 2013, the regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e) and 412.78(e) already contain provisions that set the update factor for SCHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we are not proposing to make further changes to these four regulatory provisions to reflect the FY 2013 update factor for the hospital-specific rates of SCHs.

We note that, as discussed in section IV.G. of this preamble, section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, the MDH program was to be in effect through the end of FY 2011 only. Absent additional legislation further extending the MDH program, the MDH program will expire for discharges beginning in FY 2013. Accordingly, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2013.

2. FY 2013 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Pub. L. 108–173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 2.1 percent for FY 2013. The regulations at § 412.211(c) already set the update factor for the Puerto Rico-specific operating standardized amount equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, it is not necessary for us to propose changes to the existing regulatory text.

I. Payment for Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs (§§ 412.105, 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the hospital inpatient prospective payment system (IPPS) for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The

hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident count for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than allowed by their caps, and to authorize the ''redistribution'' of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503 amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions ''in the same manner'' to the IME FTE resident caps. The regulations implementing section 5503 of the Affordable Care Act were included in the November 24, 2010 final rule with comment period (75 FR 72263).

2. New Teaching Hospitals: Proposed Change in New Program Growth From 3 Years to 5 Years

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for calculating the direct GME caps of teaching hospitals training residents in new programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, these rules also apply to the establishment of a hospital's IME cap. CMS implemented these statutory requirements in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333). Generally, under existing regulations at 42 CFR 413.79(e)(1) and 42 CFR 412.105(f)(1)(vii), if a hospital did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins to participate in training residents in a new residency program (allopathic or osteopathic) on or after January 1, 1995, the hospital's unweighted FTE resident cap (which would otherwise be zero) may be adjusted based on the product of the highest number of FTE residents in any program year during the third year of the first new program, for all new residency training programs established during that 3-year period, and the minimum accredited length for each type of program. The number of FTE resident cap slots that a teaching hospital receives for each new program may not exceed the number of accredited slots that are available for each new program. Once a hospital's FTE resident cap is established, no subsequent cap adjustments may be made for new programs unless the teaching hospital is a rural hospital. A rural hospital's FTE resident caps may be adjusted for participation in subsequent new residency training programs. As a reminder, a hospital that did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, may only receive a permanent FTE resident cap adjustment for training residents in a truly ''new'' residency training program; no permanent cap adjustment would be given for training residents associated with an existing program. That is, if a hospital that did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, serves as a training site for residents in a program that exists or existed previously at another teaching hospital that remains open, that ''new'' teaching hospital does not receive a ''new program'' cap adjustment because it is not participating in training residents in a truly ''new'' program. However, it is possible for that hospital to receive a temporary cap adjustment if the new teaching hospital enters into a Medicare GME affiliation agreement with the existing teaching hospital as specified at 42 CFR 413.79(f) and 412.105(f)(1)(vi). (For a detailed discussion of the distinctions between a new residency program and an existing residency program, we refer readers to the August 27, 2009 final rule (74 FR 43908).)

As stated previously, the existing regulations provide for a 3-year period in which a new teaching hospital can ''grow'' its programs, for the purpose of establishing its FTE resident caps. This 3-year period, which we will refer to as the ''3-year window'' for ease of reference, starts when (typically a July 1) the new teaching hospital first begins to train residents in its first new program, and it ends when the third program year of that first new program ends. For example, assume residents begin training in a new program for the first time on July 1, 2012. The 3-year window begins on July 1, 2012, and ends on June 30, 2015, the end of the third program year of that (first) new program. At this point in time, regardless of the actual accredited length of the new program, or the number of new programs started, the new teaching hospital's FTE resident caps are established permanently and are effective beginning with the fourth program year from the date the first new program started (using the same example, this would be July 1, 2015).

The provider community has expressed concerns that 3 years do not provide for a sufficient amount of time for a hospital to ''grow'' its new residency programs and to establish FTE resident caps that are properly reflective of the number of FTE residents that it will actually train, once the programs are fully grown. Providers have explained that 3 years is an insufficient amount of time primarily because a period of 3 years is not compatible with program accreditation requirements, particularly in instances where the new teaching hospital wishes to start more than one new program. For example, we understand that a new teaching hospital may not begin all of its new programs at the same time because of accreditation prerequisites; rather, a new teaching hospital must wait until the first program is in place for a specified amount of time before it can begin training residents in a second or third program. This potential delay means that a new teaching hospital may not be able to sufficiently ''grow'' all of

its new programs by the end of the ''3-year window.'' We understand, for example, that the Accreditation Council for Graduate Medical Education (ACGME) requires that, for a hospital to sponsor an anesthesiology program, the hospital must sponsor or be affiliated with at least one internal medicine program and one general surgery program. Furthermore, we understand that the ACGME can require new residency training programs to pass through an ''initial'' accreditation period of up to 3 years until they can be granted ''continued'' accreditation. During this initial accreditation period, a hospital is not allowed to add any additional positions to its new program. Therefore, even if a hospital has plans to expand its new training program beyond the number of positions for which it is initially accredited, it may not be possible for the hospital to actually do so until this initial period has expired. Lastly, we have been made aware that providers may want to stagger the start dates for their residency training programs if they plan on training residents in several programs because they may want to gain some experience in residency training before they begin all of their new programs.

Given the concerns about new teaching hospitals having insufficient time to ''grow'' their new residency training programs and to establish an appropriately reflective permanent FTE resident cap within a 3-year window, we are proposing that a new teaching hospital will have 5 years, or a ''5-year window,'' in which to establish and grow new programs. At the end of the fifth program year of the first new program in which the new teaching hospital participates, the new teaching hospital's FTE resident caps would be determined, and set permanently, effective with the beginning of the sixth program year. We are proposing that this change would apply to new teaching hospitals that begin training residents in new programs for the first time on or after October 1, 2012. Although we understand that many residency training programs begin July 1 of the calendar year, consistent with the proposed effective date of the FY 2013 IPPS provisions in this proposed rule, we are proposing an effective date for this change of October 1, 2012. We are proposing to amend the regulations at § 413.79(e)(1) to state that if a new teaching hospital participates in training residents in a new program for the first time on or after October 1, 2012, the new teaching hospital's FTE resident cap may be adjusted based on the product of the highest number of FTE residents training in any program year during the fifth year of the first program's existence for all new residency training program(s) and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. This proposed policy would apply to the establishment of a hospital's cap for both direct GME and IME payment purposes. The IME regulations at § 412.105(f)(1)(vii) refer to the direct GME regulations at § 413.79(e)(1) through (e)(4) for the rules for the establishment of a new teaching hospital's cap. As is required under existing regulations, the number of cap slots associated with each new program cannot exceed the number of accredited slots available to the hospital for that new program.

We note that we are not proposing to make any changes to regulations governing treatment of the rolling average and the intern and resident-to-bed (IRB) ratio for new programs. That is, new program FTE residents will continue to be exempt from the rolling average and the cap on the IRB ratio for the minimum accredited length for the specific type of residency training program. These exceptions are discussed in the regulations at §§ 412.105(a)(1)(i) through (a)(1)(ii) and 413.79(d)(5). The current cost report instructions for Worksheet E–4, Line 6 (current year unweighted allopathic and osteopathic FTE count) instruct hospitals to contact their Medicare contractor for instructions on how to complete that line if the hospital has a new program for which the period of years is less than or greater than 3 years. Similarly, in the case of this proposed policy where the exemption from the rolling average for a new program could expire prior to the hospital's cap being set in the sixth year of the first new program, we would encourage our Medicare contractors to contact us if they have questions on the method of reporting FTE resident counts that are subject to the rolling average but not subject to the cap.

We also are proposing to revise the regulations at § 413.79(e)(1)(i) that discuss the methodology used to calculate a new teaching hospital's cap adjustment for a new residency training program if residents training in the new program are rotating to more than one hospital during the 5-year window. This same methodology would apply to a rural teaching hospital because a rural teaching hospital can always receive a cap adjustment for starting a brand-new program. We are proposing to revise the regulations to specify that, in calculating the cap adjustment for each new program started within the 5-year window, we would look at the highest total number of FTE residents training in any program year during the fifth academic year of the first new program's existence at all participating hospitals involved and multiply that highest FTE resident count by the number of years in which residents are expected to complete the program, based on the minimum accredited length of the specific program. Furthermore, we are proposing that, for each new program started within the 5-year window, we would then take that product and multiply it by each hospital's ratio of the number of FTE residents in the new program training over the course of the 5-year period at each hospital to the total number FTE residents training at all participating hospitals over the course of the 5 years. We believe it is appropriate to propose to apportion the overall FTE cap among the hospitals participating in training residents in the new program based on the percentage of FTE residents each hospital trained over the course of the entire 5-year period, rather than the percentage of FTE residents each hospital trained only during the fifth academic year, because the trend of training over the entire 5-years may reflect more completely the patterns in the training in years subsequent to the fifth academic year. Otherwise, a hospital's FTE cap adjustment, which is permanent, may reflect too heavily the share of training time solely in the fifth academic year, which may or may not be beneficial to the hospital. We note that a hospital's cap adjustment could differ, depending on whether we look only at the fifth academic year of the first new program or look at every available year (up to 5 years) for which training occurred to calculate each hospital's share of the aggregate cap for a specific program.

In addition, we are proposing to revise the existing regulation text at § 413.79(e)(1)(i) to include the phrase ''the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program.'' This proposed language is consistent with our past, current, and proposed policy. We also note that § 413.79(e)(1) applies in instances where the residents in the new program train only at one hospital; § 413.79(e)(1)(i) applies when residents in the new program train at more than one hospital, regardless of whether each of those hospitals are new hospitals or existing teaching hospitals with previously established caps. The example below illustrates the proposed methodology of how we would calculate

a new teaching hospital's cap (or rural teaching hospital's cap) if we changed the cap-building period from 3 years to 5 years. In this example, as explained above, we are proposing that we would calculate the cap based on what is occurring at the new teaching hospital(s) during the fifth academic year of the new teaching hospital's first new program (or the fifth academic year of the rural teaching hospital's new residency training program). The provider community has requested that the cap-building period be increased from 3 years to 5 years. Therefore, we are proposing that we would only look at the training that is occurring during the fifth academic year of the first new program to calculate the aggregate cap adjustment. However, we would look at the FTE residents training at the hospital(s) during all 5 years to determine how we would distribute the aggregate cap adjustment among the participating hospitals.

Example: Hospital A is a hospital that becomes a new teaching hospital by training residents in a new family medicine program in academic year 1. Within its 5-year window, it also begins a new surgery program in academic year 4 of the first new program, the family medicine program. The family medicine program is accredited for 15 positions, 5 positions per year (the minimum accredited length of a family medicine program is 3 years). The surgery program is accredited for 20 positions, 4 positions per year (the minimum accredited length of a surgery program is 5 years). Residents in both the family medicine program and the surgery program also rotate to Hospital B. Hospital B is an existing teaching hospital (nonrural) with a cap that is already established; therefore, it will not receive any cap adjustments for training FTE residents in the new family medicine program or the new surgery program. However, because both of these programs are approved programs and FTE residents are training at Hospital B for part of the time, Hospital B can count the FTE residents training in the family medicine program and the surgery program at its facility if it has room under its caps to do so.

First, we will determine the cap adjustment that Hospital A will receive for training FTE residents in the family medicine program. The following table includes the allowable FTE resident counts in the family medicine program at both Hospital A and Hospital B during the 5-year window. These numbers are FTE resident counts because they reflect the share of training time spent at Hospital A and Hospital B, and also assume for this example that we have excluded some nonallowable time, such as the time residents spend training in didactic activities in a medical school lecture hall.

HOSPITAL A

Year 1	Year 2	Year 3	Year 4	Year 5
0.75 PGY 1	2.60 PGY 1	4.00 PGY 1	4.10 PGY 1	4.20 PGY 1.
0.00 PGY 2	2.80 PGY 2	3.40 PGY 2	3.40 PGY 2	3.70 PGY 2.
0.00 PGY 3	0.00 PGY 3	2.40 PGY 3	2.80 PGY 3	2.80 PGY 3.
Total 0.75	Total 5.40	Total 9.80	Total 10.30	Total 10.70.

Hospital A's 5 year total = 36.95.

HOSPITAL B

Year 1	Year 2	Year 3	Year 4	Year 5
3.75 PGY 1	2.20 PGY 1	0.90 PGY 1	0.80 PGY 1	0.60 PGY 1.
0.00 PGY 2	2.00 PGY 2	1.50 PGY 2	1.50 PGY 2	1.20 PGY 2.
0.00 PGY 3	0.00 PGY 3	2.40 PGY 3	2.00 PGY 3	2.00 PGY 3.
Total 3.75	Total 4.20	Total 4.80	Total 4.30	Total 3.80.

Hospital B's 5 year total = 20.85.

Total Hospital A and Hospital B over 5 years = 36.95 + 20.85 = 57.80 FTEs.

To calculate the cap adjustment for Hospital A with respect to the family medicine program, we need to take the highest number of FTE residents training in any program year in the program (that is, FTE residents training at both Hospital A and Hospital B) in the fifth academic year of the first new program (which is the family medicine program). If we add the PGY 1s, the PGY 2s, and the PGY 3s at both hospitals, in year 5, we see that we would use the total number of PGY 2s to calculate the FTE cap adjustment for the family medicine program, because the total number of PGY 2s at both hospitals is 4.90 FTEs (3.70 + 1.20), whereas the total number of PGY 1s and PGY 3s is only 4.80. We multiply 4.90 by the minimum accredited length of the family medicine program to get the total possible cap adjustment for the family medicine program (4.90 × 3 = 14.70). The cap adjustment that Hospital A receives for the family medicine program will be some number less than 14.70 based on the ratio of the number of FTEs in the new program training over the course of the 5-year period at Hospital A to the total number FTE residents training at both hospitals over the course of the 5 year period.

To determine this ratio, note that Hospital A's total FTE residents in the new family medicine program over the course of 5 years is the numerator, 36.95. The total FTE residents at Hospitals A and B in the new family medicine program over the course of 5 years is the denominator, 57.80 (that is, 36.95 + 20.85). The ratio of training that occurred at Hospital A is 36.95/57.80 = 0.64. Therefore, Hospital A's cap for its share of the family medicine program is 0.64 × 14.70, or 9.41. (If Hospital B had been eligible to receive a cap adjustment, its ratio of the cap would have been 0.36, that is, (20.85/57.80), and its share would have been 5.30 (0.36 × 14.70). If we add 9.41 to 5.30, we get 14.71 (we note that 14.71 is ''approximately'' equal to 14.70, the total cap determined for the entire family medicine program, with a slight difference due to rounding). Thus, we have ensured that, in assigning a cap of 9.41 to Hospital A on behalf of its family medicine program, the total allowable and accredited number of slots has not been exceeded).

Now we will determine the cap adjustment that Hospital A will receive for training FTE residents in the new

surgery program that began in year 4 of the first new program. The following tables include the allowable FTE resident counts in the surgery program at Hospital A and Hospital B, respectively, during the hospital's 5-year window. Again, assume we have excluded nonallowable time, such as time residents spent training in didactic activities in a medical school lecture hall.

HOSPITAL A

Year 1	Year 2	Year 3	Year 4	Year 5.
0.00 PGY 1	0.00 PGY 1	0.00 PGY 1	4.10 PGY 1	4.20 PGY 1.
0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	2.70 PGY 2.
0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3.
0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4.
0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.
Total 0.00	Total 0.00	Total 0.00	Total 4.10	Total 6.90.

Hospital A's 5 year total = 11.00.

HOSPITAL B

Year 1	Year 2	Year 3	Year 4	Year 5
0.00 PGY 1	0.00 PGY 1	0.00 PGY 1	1.70 PGY 1	0.60 PGY 1.
0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	1.50 PGY 2.
0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3.
0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4.
0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.
Total 0.00	Total 0.00	Total 0.00	Total 1.70	Total 2.10.

Hospital B's 5 year total = 3.80.

Total Hospital A and Hospital B over 5 years = 11.00 + 3.80 = 14.80 FTEs.

To calculate the cap adjustment for Hospital A with respect to the surgery program, we need to take the highest number of FTE residents training in the program (that is, FTE residents training at both Hospital A and Hospital B) in the fifth academic year of the first new program (which is the family medicine program). Because the surgery program only started in Year 4 of the family medicine program, there are only PGY 1s and PGY 2s training at both Hospitals A and B in year 5. If we add the PGY 1s and the PGY 2s at both hospitals in year 5, we see that we would use the total number of PGY 1s to calculate the FTE cap adjustment for the surgery program, because the total number of PGY 1s is 4.80 FTEs (4.20 + 0.60), whereas the total number of PGY 2s is only 4.20. We multiply 4.80 by the minimum accredited length of the surgery program to get the total possible cap adjustment for the surgery program ($4.80 \times 5 = 24.00$). However, because the surgery program is only accredited for 20 positions, the overall FTE resident cap associated with the surgery program that is to be apportioned between Hospital A and Hospital B is limited to a maximum of 20. In this instance, because the surgery program started in Year 4 of the family medicine program, and it only ''grew'' for 2 years, we only have 2 years of FTE resident counts to consider and not 5 years. Nevertheless, the cap adjustment that Hospital A receives for the surgery program will be some number less than 20 and is based on the ratio of the number of FTE residents in the new program training over the course of the 2-year period at Hospital A to the total number of FTEs training at both hospitals over the course of the 2-year period.

To determine this ratio, note that Hospital A's total FTE residents in the new surgery program over the course of 2 years is the numerator, 11.00. The total number of FTE residents at Hospitals A and B in the new surgery program over the course of 5 years is the denominator, 14.80 (that is, 11.00 + 3.80). The ratio of training that occurred at Hospital A is 11.00/14.80 = 0.74. Hospital A's cap for its share of the surgery program is $0.74 \times 20 = 14.80$. (If Hospital B had been eligible to receive a cap adjustment, its share of the cap would have been 5.20 ($(3.80/14.80) \times 20$) = 5.20. Thus, we have ensured that, in assigning a cap of 14.80 to Hospital A on behalf of its surgery program, the total allowable and accredited number of slots has not been exceeded).

Adding together the cap adjustment Hospital A receives for the new family medicine program and the cap adjustment it receives for the new surgery program, Hospital A's total permanent cap is 24.21 (9.41 + 14.80 = 24.21).

In summary, we are proposing to revise the regulations at § 413.79(e)(1) for the purposes of direct GME and, by reference, § 412.105(f)(1)(vii) for purposes of IME to state that if a hospital begins training residents in a new program for the first time on or after October 1, 2012, that hospital's caps may be adjusted based on the product of the highest number of FTE residents training in any program year during the fifth academic year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The cap would be applied beginning with the sixth academic year of the first new program. We also are proposing conforming changes throughout paragraph (e)(1) of § 413.79 to correspond with the proposed change to increase the length of the cap-building period from 3 to 5 years. In addition, we are proposing to change the regulation text at § 413.79(e)(1)(i) to reflect a methodology to calculate a new teaching hospital's cap adjustment if the residents in the new training program are training at more than one hospital. We are proposing that these changes would be effective for a hospital that begins training residents for the first time on or

after October 1, 2012. Lastly, we are making a clarification to the existing regulation text at § 413.79(e)(1)(i) to insert the missing phrase ''and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program.'' This change is consistent with our past, current, and proposed policy.

3. Clarification Related to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 5503 of the Affordable Care Act

As previously discussed, in an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps, while other hospitals are training a number of allopathic and osteopathic residents at some level below their FTE resident caps. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for reductions in the statutory FTE resident caps for direct GME payment purposes under Medicare for certain hospitals that are training allopathic and osteopathic residents at a level below their FTE resident caps, and to authorize a ''redistribution'' to certain hospitals of the estimated number of FTE resident slots resulting from the reductions. Section 5503 of the Affordable Care Act also amended section 1886(d)(5)(B)(v) of the Act to require application of the provisions of section 1886(h)(8) of the Act ''in the same manner'' to the FTE resident caps for IME payment purposes.

Section 1886(h)(8)(A)(i) of the Act provides that, effective for portions of cost reporting periods occurring on or after July 1, 2011, a hospital's FTE resident cap will be reduced by 65 percent of the difference between the hospital's ''otherwise applicable resident limit'' and its ''reference resident level,'' if its ''reference resident level'' is less than its ''otherwise applicable resident limit'' (as defined at section 1886(h)(8)(H) of the Act). (We refer readers to the November 24, 2010 final rule with comment period (75 FR 72155 through 72161) for a discussion of these terms.) Section 1886(h)(8)(A)(ii) of the Act and the November 24, 2010 final rule with comment period (75 FR 72147) describe which hospitals are exempt from a cap reduction under section 5503 of the Affordable Care Act, including rural hospitals with fewer than 250 acute care inpatient beds.

Under section 1886(h)(8)(B) of the Act, the Secretary is authorized to increase the FTE resident caps for certain categories of hospitals for portions of cost reporting periods occurring on or after July 1, 2011, in the aggregate, by a number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(8)(A) of the Act. In determining which hospitals will receive an increase in their FTE resident caps, sections 1886(h)(8)(C) through 1886(h)(8)(E) of the Act direct us to do all of the following:

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2011.
- Take into account whether the hospital has an accredited rural training track program.
- Distribute 70 percent of the resident slots to hospitals located in States with resident-to-population ratios in the lowest quartile.
- Distribute 30 percent of the resident slots to hospitals located in a State, a territory of the United States, or the District of Columbia that are among the top 10 States, territories, or the District in terms of the ratio of the total population living in an area designated as a health professional shortage area (HSPA), as of March 23, 2010, to the total population, and/or to hospitals located in rural areas.

A comprehensive description of the rules implementing the cap slot redistribution under section 1886(h)(8) of the Act can be found in the November 24, 2010 final rule with comment period (75 FR 72168). Section 1886(h)(8)(B)(ii) of the Act, as added by section 5503(a)(4) of the Affordable Care Act, specifies that a hospital that receives an increase in its cap shall ensure, during the 5-year period beginning on the date of such increase (July 1, 2011), that certain requirements, referred to as the primary care average and the 75-percent threshold, are met in order to retain those slots. Otherwise, section 1886(h)(8)(B)(iii)(I) of the Act authorizes the Secretary to reduce the FTE resident caps of the hospital by the same number of FTE residents by which the hospital's FTE resident caps were increased if the hospital fails to meet either requirement; and section 1886(h)(8)(B)(iii)(II) of the Act authorizes the Secretary to redistribute those positions.

Specifically, section 1886(h)(8)(B)(ii) of the Act states, ''* * * a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) The number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of fulltime equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and

(II) Not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.''

In a case where the Secretary determines that a hospital did not meet the requirements in a cost reporting year during the 5-year time period, section 1886(h)(8)(B)(iii) of the Act states that ''* * * the Secretary shall—

(I) Reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) Provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.''

In the November 24, 2010 final rule with comment period (75 FR 72195 through 72203), we stated that the ''5-year period beginning on the date of such increase'' is July 1, 2011 through June 30, 2016, and we provided a detailed discussion of what the two requirements under sections 1886(h)(8)(B)(ii)(I) and 1886(h)(8)(B)(ii)(II) of the Act entail. In that final rule, we noted that section 1886(h)(8)(B)(ii) of the Act allows the Secretary to ''determine whether a hospital has met the requirements * * * during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period,'' and section 1886(h)(8)(B)(iii) of the Act instructs the Secretary to ''reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased * * *.'' We also explained that we believe the Secretary has the discretion to consider a hospital's performance over more than one year or

to review each year during the 5 years independently in determining whether or not a hospital is in compliance with the primary care average and the 75-percent threshold, as required (75 FR 72196 and 72197 and 72200 and 72201). We emphasized that it is within CMS' and the Medicare contractors' authority to adjust a hospital's IME and direct GME payments as early as it is feasible within a cost report's submission and review cycle, and that we need not wait until final settlement to do so. We further stated in the November 24, 2010 final rule with comment period implementing section 5503 that ''We also understand that we should consider that hospitals might not immediately fill all the slots they receive, particularly because they are only required to demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011'' (75 FR 72197). However, we gave an example that indicated that, of the section 5503 FTE slots that the hospital does begin to use, 75 percent of those slots must be in primary care or general surgery.

Since we awarded the section 5503 slots pursuant to section 1886(h)(8) of the Act, we have received questions from hospitals asking if and how CMS would enforce the primary care average and the 75-percent threshold requirements under sections 1886(h)(8)(B)(ii)(I) and 1886(h)(8)(B)(ii)(II) of the Act if a hospital does not use any of its section 5503 slots until year 4 or year 5 of the 5-year period, or if a hospital does not use any of the section 5503 slots until after expiration of the 5-year period. We have informed hospitals that the 75-percent threshold requirement applies once the hospital starts using any of the section 5503 slots, and the 3-year primary care average requirement applies immediately on July 1, 2011, regardless of whether or not the hospital begins to use its additional section 5503 slots in year 1 of the 5-year period. This is because the 3-year primary care average test applies to the hospital's pre-section 5503 resident complement as well, and not exclusively to the additional FTE residents associated with slots awarded under section 5503.

In determining which hospitals applying for slots under section 5503 will receive slots, section 1886(h)(8)(C)(i) of the Act specifies that the Secretary shall take into account the demonstrated likelihood of the hospital filling the slots within the first three cost reporting periods beginning on or after July 1, 2011. Hospitals included evidence supporting the demonstrated likelihood stipulation in their applications and we took that into consideration in awarding slots under section 5503. We believe that it is inappropriate and in direct conflict with a base consideration in the awarding of slots under section 5503 for hospitals to refrain from using their section 5503 slots until after the initial 3 years after the slots have been awarded in an attempt to circumvent the primary care average or the 75-percent threshold requirements, or both.

As stated in the November 14, 2010 final rule, CMS reserves the right to assess as many times as necessary in the 5-year period whether a hospital is meeting the required criteria. The agency also may remove the slots awarded to a hospital at any point during the 5-year period (75 FR 72196 and 72197 and 72200 and 72201). Because a statutorily directed criterion for consideration in awarding slots under section 5503 included the requirement that hospitals applying for slots demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, and we relied on that information in awarding slots, we believe it is reasonable to expect that hospitals that received slots under section 5503 should begin to use their slots within the first three 12-month cost reporting periods beginning on or after July 1, 2011, of the 5-year period in order to give full effect to the requirements under section 1886(h)(8)(B)(ii) of the Act. Therefore, we are proposing that a hospital must fill *at least half* of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes, or lose its section 5503 slots: (A) in its first 12-month cost reporting period of the 5-year period; and/or (B) in its second 12-month cost reporting period of the 5-year period; and/or (C) in its third 12-month cost reporting period of the 5-year period. For example, Hospital A and Hospital B both have June 30 fiscal year ends (FYEs), and they received 10 slots under section 5503. In its FYE June 30, 2012, Hospital A filled 8 slots. In its FYE June 30, 2013, Hospital A filled 0 slots. In its FYE June 30, 2014, Hospital A filled 5 slots. However, Hospital B, in its FYEs June 30, 2012, 2013, and 2014, only filled 3 slots respectively in each of the 3 years. Hospital A would have complied with our proposed requirement, because it filled at least half of its section 5503 slots in either its first, and/or second, and/or its third 12-month cost reporting period during the 5-year period. Hospital B would not have complied with our proposed requirement because in neither its first, second, or third 12-month cost reporting period had it filled at least 5 (half of 10) slots.

We are proposing to interpret that a hospital's failure to use slots awarded under section 5503 in a timely manner to also be a failure to meet the 75-percent threshold. We believe that we have the authority to interpret section 1886(h)(8)(B)(ii) of the Act in such a manner and to propose this requirement because section 1886(h)(8)(B)(ii) of the Act allows the Secretary to ''* * * determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.'' We are reiterating that the 75-percent threshold applies in the instance where a hospital *uses less than half, or any amount,* of its slots prior to its third 12-month cost reporting period during the 5-year period (75 FR 72197). In other words, the 75-percent threshold applies throughout the 5-year period, as long as the hospital is using some amount of its section 5503 slots in the respective cost reporting period. If a hospital is using some of its section 5503 slots in a cost reporting period, the 75-percent threshold would be enforced; if a hospital is not using any of its section 5503 slots in a cost reporting period, the 75-percent threshold would not be enforced. However, as stated earlier, we are proposing that a hospital must use its section 5503 slots no later than the hospital's third 12-month cost reporting period (and that at least half of its section 5503 slots must be used in either the first, or second, or third 12-month cost reporting period).

We note that we did not specify that a hospital must use at least half of its section 5503 slots in its third 12-month cost reporting period of the 5-year period in the November 24, 2010 final rule with comment period because the possibility that a hospital might not begin to use its section 5503 slots for several years only came to our attention after July 1, 2011, in response to questions raised by hospitals. Furthermore, given the huge demand for these slots (to the extent that we ran out of slots during the redistribution process and were unable to award any slots to hospitals in qualifying, but lower ranking, States), and that the slots were slated to be distributed in States where there was an acute need for additional residents (that is, as sections 1886(h)(8)(D) and 1886(h)(8)(E) of the Act specify, to States with resident-to-population ratios in the lowest quartile, and to States that are among the top 10 in terms of the HPSA population to total

population ratios), we did not expect that hospitals that received section 5503 slots would not be able to make almost immediate use of the slots. Consequently, given the presumed huge need for these slots in the States where Congress directed that they be awarded, we believe it is appropriate to use our authority to reasonably ensure that those slots awarded are used in compliance with section 5503 (hence, the proposals in this proposed rule), and, if not, are able to be redistributed to other hospitals in need of slots as Congress intended.

Section 1886(h)(8)(B)(iii) of the Act states that if the Secretary determines that a hospital does not meet either the primary care average or the 75-percent threshold, ''the Secretary shall (I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and (II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.'' Accordingly, we are exercising the broad authority that the Secretary is given to determine whether the requirements at section 1886(h)(8)(B)(ii) of the Act are met by proposing that if a hospital fails to fill at least half of its section 5503 slots, IME and direct GME respectively, in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period, and/or in its third 12-month cost reporting period of the 5-year period, this would mean failure to meet the 75-percent threshold. In the case of such failure, CMS would instruct the Medicare contractor after audit to permanently remove all of the hospital's section 5503 slots from the earliest cost reporting period that is subject to reopening and in which it would be determined that the hospital did not meet the requirements (in accordance with existing § 413.79(n)(2)(iii), which is proposed to be redesignated as § 413.79(n)(2)(iv) in this proposed rule), even if the hospital had used at least half of its section 5503 slots in its fourth or subsequent cost reporting year of the 5-year period. Thus, as part of the Medicare contractors' reviews of the hospitals that received section 5503 slots, we are proposing that the Medicare contractors would determine whether a hospital filled at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. We believe it is appropriate to remove the slots from a hospital that has not filled at least half of its slots in any 12-month cost reporting year prior to and including the third 12-month cost reporting period so that these slots may be redistributed to other hospitals that may have greater success in filling the slots and that are located in States that are described in sections 1886(h)(8)((D) and 1886(h)(8)(E) of the Act.

We note that, as explained in the November 24, 2010 final rule with comment period, the start and end of each year of the 5-year period depend on the fiscal year begin date of each hospital's cost reporting periods. Hospitals with fiscal year begin dates of July 1 will have five 12-month cost reporting periods starting on July 1, 2011, and ending on June 30, 2016, while hospitals with fiscal year begin dates of other than July 1 will have a partial cost reporting period that includes July 1, 2011, four 12-month cost reporting periods, and another partial cost reporting period that includes June 30, 2016 (75 FR 72197). For example, if Hospital A has a June 30 fiscal year end, its third 12-month cost reporting period of the 5-year period would be July 1, 2013, to June 30, 2014, and Hospital A must fill *at least half* of its section 5503 slots, IME and direct GME respectively, in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. If Hospital B has a September 30 fiscal year end, its cost reporting periods occurring during July 1, 2011 through June 30, 2016 are as follows:

Year 1—July 1, 2011–September 30, 2011

Year 2—October 1, 2011–September 30, 2012

Year 3—October 1, 2012–September 30, 2013

Year 4—October 1, 2013–September 30, 2014

Year 5—October 1, 2014–September 30, 2015

Year 6—October 1, 2015–June 30, 2016

Hospital B's third 12-month cost reporting period would be October 1, 2013, to September 30, 2014, and Hospital B must fill at least half of its section 5503 slots, IME and direct GME, respectively, in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period, and/or in its third 12-month cost reporting period of the 5-year period. As explained in the November 24, 2010 final rule with comment period (75 FR 72197), if hospitals have other than a June 30 fiscal year end, for their cost reports that include July 1, 2011 and June 30, 2016 respectively, we will consider whether the hospital meets the primary care average and the 75-percent threshold requirements based on an annualized FTE count. Also, if during the period of July 1, 2011 through June 30, 2016, hospitals, for whatever reason, actually have less than 12-month cost reports, we would consider on a case-by-case basis which cost reports we would evaluate for purposes of meeting the proposed requirement of filling at least half of the section 5503 slots in its first, second, and/or third cost reporting period. As under existing policy, if the hospital does begin to fill its section 5503 slots but fails to meet the 75-percent threshold, the Medicare contractor would also remove the section 5503 slots, effective with the earliest year that the 75-percent threshold is not met.

Lastly, considering again that hospitals that received section 5503 slots had to demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, we are proposing to require that hospitals that received section 5503 slots must fill all of the slots they received in their final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016 (IME and direct GME respectively), or lose all of their section 5503 slots after June 30, 2016. As stated above, we consider it to be appropriate to remove the slots from a hospital that has not filled at least half of its slots in any 12-month cost reporting period prior to and including the third 12-month cost reporting period, so that these slots may be redistributed to other hospitals that otherwise qualified to receive slots, but did not receive them because the available slots were granted to higher ranking hospitals. We also are interested in commenters' recommendations regarding alternative approaches to encouraging compliance with the 3-year primary care average requirement and the 75-percent threshold.

In summary, we are proposing that a hospital must fill at least half of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes or lose its section 5503 slots: (A) in its first 12-month cost reporting period of the 5-year period; and/or (B) in its second 12-month cost reporting period of the 5-year period; and/or (C) in its third 12-month cost reporting period of the 5-year period. We are proposing to enforce the 75-percent threshold test once the hospital begins to use its section 5503 slots,

which we are proposing must be no later than the hospital's third 12-month cost reporting period (and that at least half of its section 5503 slots must be used in either the first, or second, or third 12-month cost reporting period). In addition, we are proposing that a hospital does not meet the 75-percent threshold if it fails to fill at least half of its section 5503 slots, IME and direct GME, respectively, in one or a combination of the first three 12-month cost reporting period of the 5-year period, and upon that basis, CMS would instruct the Medicare contractor, after audit, to permanently remove all of the hospital's section 5503 slots from the earliest cost reporting period that is subject to reopening and in which it would be determined that the hospital did not meet the requirements (in accordance with existing § 413.79(n)(2)(iii), which is proposed to be redesignated as § 413.79(n)(2)(iv) in this proposed rule), even if the hospital had used at least half of its section 5503 slots in its fourth or subsequent cost reporting year of the 5-year period. Thus, as part of the Medicare contractors' reviews of the hospitals that received section 5503 slots, we are proposing that the Medicare contractors would determine whether a hospital filled at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period, and/or in its third 12-month cost reporting period of the 5-year period. Lastly, we are proposing to require that a hospital that received section 5503 slots must fill all of the slots it received in their final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016 (IME and direct GME respectively), or lose all of its section 5503 slots after June 30, 2016.

We are proposing that these requirements would be effective for a hospital's third 12-month cost reporting period occurring during the 5-year period of July 1, 2011 through June 30, 2016. For example, for hospitals with a June 30 fiscal year end, this would be July 1, 2013 through June 30, 2014. For hospitals with a September 30 fiscal year end, this would be October 1, 2013 through September 30, 2014. For hospitals with a December 31 fiscal year end, this would be January 1, 2014 through December 31, 2014. We are proposing to make appropriate changes to the regulations text at § 413.79(n)(2) to incorporate our proposals. The IME regulations regarding section 5503 slots that are at existing § 412.105(f)(1)(iv)(C)(2) reference the direct GME regulations text at § 413.79(n) and would not require amendments.

4. Preservation of Resident Cap Positions From Closed Hospitals (Section 5506 of the Affordable Care Act)

a. Background

Under existing regulations at § 413.79(h) for direct GME and § 412.105(f)(1)(ix) for IME, a hospital that is training FTE residents at or in excess of its FTE resident caps and takes in residents displaced by the closure of another teaching hospital may receive a temporary increase to its FTE residents caps so that it may receive direct GME and IME payment associated with those displaced FTE residents. However, those temporary FTE resident caps are associated with those specific displaced FTE residents, and the temporary caps expire as those displaced residents complete their training program. Thus, in the past, if a teaching hospital closed, its direct GME and IME FTE resident cap slots would be ''lost,'' because those cap slots are associated with a specific hospital's Medicare provider agreement, which would be retired upon the hospital's closure. Section 5506 of the Affordable Care Act addressed that situation by amending section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the total number of FTE resident cap slots distributed shall be equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively. Under existing regulations at § 489.52 and § 413.79(h), ''closure of a hospital'' means the hospital terminates its Medicare provider agreement. As finalized in the November 24, 2010 final rule with comment period (75 FR 72213), we also specified that the FTE resident cap slots of the hospital that closed no longer exist as part of any other hospital's permanent FTE resident cap.

Section 1886(h)(4)(H)(vi)(II) of the Act, as added by section 5506(a) of the Affordable Care Act, specifies that the Secretary shall distribute the FTE cap increases in the following priority order, ''with preference given within each category to hospitals that are members of the same affiliated group'' (as defined by the Secretary) as the closed hospital:

- First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.
- Second, to hospitals located in the same State as the closed hospital.
- Third, to hospitals located in the same region of the country as the hospital that closed.
- Fourth, only if the slots are not able to be fully distributed under the third priority group, to qualifying hospitals in accordance with the criteria established under section 5503 (''Distribution of Additional Residency Positions'') of the Affordable Care Act.

For a detailed discussion on these ranking categories, we refer readers to the November 24, 2010 final rule with comment period (75 FR 72214 and 72215). In the November 24, 2010 final rule with comment period (75 FR 72212 through 72240), we also finalized the following Ranking Criteria:

☐ *Ranking Criterion One.* The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program(s) exactly as it had been operated by the hospital that closed (that is, same residents, possibly the same program director, and possibly the same (or many of the same) teaching staff).

☐ *Ranking Criterion Two.* The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital *received* slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, preference would be given to an applying hospital that was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement.

□ *Ranking Criterion Three.* The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).

□ *Ranking Criterion Four.* The applying hospital does not fit into Ranking Criteria One, Two, or Three, and will use additional slots to establish a new or expand an existing geriatrics residency program.

□ *Ranking Criterion Five:* Applying hospital does not meet Ranking Criterion One, Two, or Three, is located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.

□ *Ranking Criterion Six:* Applying hospital does not meet Ranking Criterion One, Two, or Three, is not located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.

□ *Ranking Criterion Seven:* Applying hospital seeks the slots for purposes that do not fit into any of the above ranking criteria.

In determining which hospitals should receive the slots associated with the closed hospital, in addition to considering the ranking categories and criteria listed above, section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, states that the Secretary may only award slots to an applying hospital ''if the Secretary determines that the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.'' ''Within 3 years'' means within the 3 academic years immediately following the application deadline to receive slots after a particular hospital closes (75 FR 72224). For example, where the application deadline is April 1, 2011, the immediately following academic year is July 1, 2011; therefore, hospitals must demonstrate the likelihood of filling their slots by June 30, 2014.

Finally, section 5506(d) of the Affordable Care Act specifies that ''the Secretary shall give consideration to the effect of the amendments made by this section on any temporary adjustment to a hospital's FTE cap under § 413.79(h) * * * (as in effect on the date of enactment of this Act) in order to ensure that there is no duplication of FTE slots * * *.'' In distributing slots permanently under section 5506, we need to be cognizant of the number of FTE residents for whom a temporary FTE cap adjustment was provided under existing regulations at § 413.79(h), and when those residents will complete their training, at which point the temporary slot associated with those displaced residents would be available for permanent redistribution.

b. Proposed Change in Amount of Time Provided for Submitting Applications Under Section 5506 of the Affordable Care Act

In the August 3, 2010 proposed rule (75 FR 46422), we proposed to establish an application process for hospitals to apply to CMS to receive an increase in FTE caps based on slots from closed hospitals. Section 5506 of the Affordable Care Act did not specify an application deadline for hospitals to request an increase to their caps when a hospital closes. With respect to the first application process, which applied to all teaching hospital closures between March 23, 2008, and August 3, 2010, we established an application deadline of April 1, 2011. For future teaching hospital closures, we finalized a policy whereby we would inform the public through an appropriate medium that increases to hospitals' FTE resident caps are available for distribution due to the closure of a teaching hospital, and the application deadline would be 4 months following the issuance of that notice to the public (75 FR 72215).

Some representatives of the provider community have commented that providing hospitals with 4 months following the announcement of a teaching hospital closure to apply for slots under section 5506 is longer than necessary. They asserted that such a long application period unnecessarily delays CMS' review of applications and the resulting distribution of resident cap slots from closed hospitals to the applicants. The provider representatives suggested that perhaps a 2-month application window is sufficient and is more practical.

We have considered the suggestion of the provider representatives, and after our initial experience in implementing section 5506 of the Affordable Care Act, we agree that 4 months may be more time than is needed for hospitals to properly prepare and submit section 5506 applications to CMS. Accordingly, as recommended, we are proposing to set the application deadline for future section 5506 applications to be 60 days following CMS' public notice of a hospital's closure and the availability of resident cap slots increases. We believe that reducing the application submission timeframe from 4 months to 60 days will shorten the entire process for awarding FTE resident cap slots from closed hospitals considerably.

c. Proposed Change to the Ranking Criteria Under Section 5506

In the November 24, 2010 final rule with comment period (75 FR 72223), we finalized the Ranking Criteria within each of the three first statutory priority categories (that is, same or contiguous CBSAs, same State, and same region) to be used to rank applications. For each application, we assigned slots based on Ranking Criteria, with Ranking Criterion One being the highest ranking and Ranking Criterion Seven being the lowest. For a complete list of the Ranking Criteria, we refer readers to section IV.I.4.a. of this preamble, which discusses the background for preservation of resident cap positions from closed hospitals under section 5506 of the Affordable Care Act. For a detailed discussion of the ranking categories, we refer readers to the November 24, 2010 final rule with comment period (75 FR 72212 through 72240).

After reviewing applications from the first section 5506 application process (those applications that were due to CMS on April 1, 2011), we observed that the overwhelming majority of applications fell under Ranking Criterion Seven, that is, the applying hospital seeks the slots for purposes that do not fit into any of Ranking Criterion One through Ranking Criterion Six. These applications included applications from hospitals that applied for FTE cap slots for *both* primary care and/or general surgery and for nonprimary care specialties as well as applications for general cap relief. The sheer number of applications we received under Ranking Criterion Seven was indicative of a need to further prioritize among the applicants that would have qualified under Ranking Criterion Seven. Therefore, we are proposing to replace current Ranking Criterion Seven with the two separate proposed Ranking Criteria listed below. We note that we are not proposing to make any changes to Ranking Criteria One through Six. We are proposing the following two criteria to replace existing Ranking Criterion Seven:

- *Proposed Ranking Criterion Seven:* The program does not meet Ranking Criterion One through Six, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.
- *Proposed Ranking Criterion Eight:* Applying hospital seeks the slots for

purposes that do not fit into any of the above ranking criteria.

Our proposal to modify Ranking Criterion Seven is consistent with current Medicare policy goals to increase residency training in primary care and general surgery, because we are proposing to give a higher ranking to those applications from hospitals applying for primary care and general surgery FTE cap slots, as well as nonprimary care programs. Under the current Ranking Criteria, when a hospital applies for additional FTE cap slots for primary care and/or general surgery as well as nonprimary care programs, we do not distinguish between the primary care/general surgery and nonprimary care applications. Therefore, because the hospital would be applying for nonprimary program(s), all the hospital's applications would fall under proposed Ranking Criterion Seven. Under this proposal, although the hospital's application that requests FTE cap slots for primary care/general surgery would qualify for proposed Ranking Criterion Seven, the application for nonprimary care/general surgery would be classified as proposed Ranking Criterion Eight.

Following is an example of how the proposed Ranking Criteria Seven and Eight would be assigned:

Hospital A applies for slots from closed Hospital B. Hospital A is seeking to expand its internal medicine and dermatology programs. Under the current ranking system, both of Hospital A's applications would receive consideration under Ranking Criterion Seven. That is, the internal medicine application is ranked equally with the dermatology application even though internal medicine is a primary care specialty. Under the proposed change to the Ranking Criteria, Hospital A's internal medicine program would receive consideration under proposed Ranking Criterion Seven while the dermatology program would receive consideration under proposed Ranking Criterion Eight.

d. Effective Dates of Slots Awarded Under Section 5506

As stated previously, section 5506(d) of the Affordable Care Act instructs the Secretary, in pertinent part, ''* * * to ensure that there is no duplication of FTE slots. * * *'' Accordingly, in distributing slots permanently under section 5506, we need to be cognizant of the number of FTE residents for whom a temporary FTE cap adjustment was provided under existing regulations at § 413.79(h), when those residents will complete their training, and at which point the temporary slots associated with those displaced residents would be available for permanent redistribution. With that in mind, in the first distribution of section 5506 cap slots from hospitals that closed between March 23, 2008, and August 3, 2010, we used the following several effective dates based on the ranking criterion under which a hospital applied:

- Date of hospital closure. This effective date could have applied to Ranking Criterion Two. It also could have applied to Ranking Criteria One and Three if there were no temporary cap adjustments given for any displaced FTE residents.
- Cost reporting period following date of hospital closure. This effective date could have been used for awarding slots to hospitals that were training displaced FTE residents and qualified for Ranking Criterion One or Ranking Criterion Three because they were taking over an entire program or part of a program from a closed hospital and had received a temporary cap adjustment to train those displaced residents under 42 CFR 413.79(h).
- July 1 effective date. This effective date, which could have been retroactive, could have been used for awarding slots to hospitals that qualified under Ranking Criteria Four through Seven where there were temporary cap adjustments made for displaced FTE residents that completed training in a program on a specific June 30.
- Date of award announcement (January 30, 2012). This effective date could have applied to hospitals that qualified under Ranking Criteria Four through Seven either where there were no temporary cap increases under 42 CFR 413.79(h), or where there were temporary cap increases but those slots associated with the temporary cap increases were already accounted for. That is, displaced FTE residents graduated prior to a specific July 1, and, therefore, the cap slots associated with these FTE residents had already been permanently assigned that specific July 1, but the closed hospital still had remaining cap slots available for permanent assignment.

Based on comments we have received from hospitals that were involved in the initial phase of section 5506 implementation (hospitals that applied for cap slots from hospitals that closed between March 23, 2008 and August 3, 2010), we believe we need to clarify certain existing policies and propose a change to the effective dates associated with several ranking criteria.

First, we are clarifying the effective date of slots awarded under section 5506 with respect to Ranking Criterion Two. Ranking Criterion Two applies to hospitals that participated in a Medicare GME affiliation agreement with the closed hospital (but not one that was entered into more than 5 years prior to the hospital's closure), received slots from the closed hospital as part of the affiliation agreement, and will use any additional awarded slots to continue to train at least the same number of FTE resident slots it trained as part of the affiliation agreement. For hospitals that qualify for additional slots under Ranking Criterion Two, we award the 5506 slots effective on a permanent basis with the date of the hospital's closure. However, for hospitals that qualify under Ranking Criteria One and Three and are already receiving temporary cap adjustments for displaced FTE residents under 42 CFR 413.79(h), we award the 5506 slots effective on a permanent basis with the cost reporting period following the date of the hospital's closure. Because these hospitals are already receiving temporary cap adjustments for their portion of their cost reporting period following the closure, for administrative ease, slots became permanent due to the section 5506 award effective with the cost reporting period following the date of the hospital's closure. However, this policy, applicable to hospitals that qualify under Ranking Criterion One or Three, is not appropriate for hospitals that qualify under Ranking Criterion Two and that participated in a Medicare GME affiliation agreement with the closed hospital and received cap slots from the closed hospital as part of that affiliation agreement. This policy is not appropriate because, in this case, there were no displaced FTE residents from the Medicare GME affiliation agreement and, therefore, the hospital did not receive a temporary cap adjustment. For example, if Hospital A received slots from Hospital B as part of an affiliation agreement so that FTE residents could train at Hospital A and Hospital B closes, Hospital A lost the cap adjustment it received from Hospital B as part of the affiliation agreement as of the date of the hospital's closure, and a temporary cap adjustment under 42 CFR 413.79(h) is not available to Hospital A. In this case, no FTE residents are displaced.

In this proposed rule, we are clarifying that, for hospitals qualifying under Ranking Criterion Two that are awarded cap slots from the closed hospital, the award is effective with the date of the hospital's closure. This effective date allows a hospital applying under Ranking Criterion Two to receive funding for training the additional FTE

residents it was training as part of the Medicare GME affiliation agreement with the closed hospital immediately after the closure, without having to wait until the following cost reporting period to receive that cap adjustment. We note that, under existing regulations at 42 CFR 413.79(d), additional FTEs that a hospital receives under the terms of a Medicare GME affiliation agreement are subject to the 3-year rolling average. Therefore, hospitals that receive permanent assignment of FTE resident cap slots under Ranking Criterion Two do not receive an exemption from the rolling average. With regard to the IME intern and resident-to-bed (IRB) ratio, the existing regulations at 42 CFR 412.105(a)(1)(i) indicate that the numerator of the prior year IRB ratio may be adjusted to reflect FTEs added under a Medicare GME affiliation agreement. The affiliation agreement would terminate when the hospital closes. Thus, on the cost report of the hospital that receives slots under Ranking Criterion Two, the prior year numerator of the IRB ratio would only be adjusted to reflect the *portion* of the affiliated FTEs that the hospital received *prior* to the other hospital's closure and the termination of the affiliation agreement.

We also are clarifying that when there are *no* temporary cap adjustments for displaced FTE residents from hospitals that closed, and an applying hospital qualifies under Ranking Criterion One or Ranking Criterion Three, the FTE resident cap slots are awarded effective with the date of the hospital's closure. This was indicated in the November 24, 2010 final rule with comment period (75 FR 72225), but we understand, based on comments received after the initial phase of section 5506 slot awards, that this policy was not clearly understood. These slots are also immediately included in applying the rolling average and IRB ratio cap.

We are proposing to change the effective date of an award of additional FTE caps for hospitals that qualify under Ranking Criterion Four through proposed Ranking Criterion Eight where temporary caps were given for displaced FTE residents (we refer readers to section IV.I.4.b. of this preamble for a discussion of proposed Ranking Criteria Seven and Eight). As a general matter, hospitals that apply under Ranking Criterion Four through proposed Ranking Criterion Eight are applying either to establish or expand a program or to seek cap relief. We do not believe that, when a hospital receives additional cap slots to establish or expand a residency training program, we need to award the cap slots retroactively to a previous July 1 effective date. Rather, the awarded cap slots are to be used on a prospective basis to allow hospitals to expand current programs or establish new ones. We understand that if a hospital is applying for cap relief under proposed Ranking Criterion Eight (current Ranking Criterion Seven), the hospital would want its cap slots awarded retroactively to the date of the hospital's closure or the July 1 after a specific displaced resident has graduated if that date is prior to the date of the award announcement. However, we do not believe such a policy is consistent with the spirit of the BBA caps. Furthermore, the purpose of section 5506 is for hospitals to receive slots from the closed hospital to facilitate the continuity of the closed hospital's programs and to promote stability in the number of physicians in a community. The proposed Ranking Criterion Eight of section 5506 does not serve to encourage the continuity of the closed hospital's programs; it merely provides Medicare funding for a certain amount of slots in excess of the BBA caps. Accordingly, we believe that hospitals applying for cap relief under proposed Ranking Criterion Eight should only receive their permanent cap slots effective on a prospective basis. Therefore, while under the initial section 5506 application process, it was possible for an applying hospital that qualified under Ranking Criteria Four through Seven to receive slots retroactive to the July 1 after a specific displaced FTE resident's graduation date, we are proposing that, for hospitals that qualify under Ranking Criteria Four through Eight for cap slots from a closed hospital even where there were temporary caps given for displaced FTE residents, the applying hospitals would receive the permanent FTE cap slots effective no earlier than the date of the award announcement. That is, if an applying hospital that qualified under Ranking Criterion Four through proposed Ranking Criterion Eight receives cap slots associated with a displaced FTE resident and that resident graduated prior to the date of the award announcement, the earliest the applying hospital could receive the permanent cap adjustment would be the date of the award announcement. If a hospital qualified under Ranking Criterion Four through proposed Ranking Criterion Eight, and the only available cap slots are temporarily being used to train displaced FTE residents that are expected to graduate *after* the date of the award, the applying hospital will receive the permanent slots effective the July 1 *after* those displaced FTE residents complete their training. For example, if a hospital closed January 1, 2012, and the section 5506 slot awards were announced May 1, 2013, but residents displaced from the closed hospital did not complete their training until June 30, 2013, the applying hospital will receive section 5506 slots for those displaced residents effective July 1, 2013, following the completion of training of those displaced residents. We are not proposing to change the effective date of section 5506 awards for applying hospitals that qualify under Ranking Criterion Four through proposed Ranking Criterion Eight where there were no temporary caps given for displaced residents; as described in the November 24, 2010 final rule with comment period (75 FR 72227), those applying hospitals will continue to receive their section 5506 cap slots effective with the date of the award announcement.

Alternatively, another option to consider for the effective date of Ranking Criteria Four through proposed Ranking Criterion Seven, which are ranking criteria associated with either starting a program or expanding a program, would be to award the slots in accordance with when the hospital actually needs the slots, as asserted in the hospital's section 5506 application. (The proposed effective date for proposed Ranking Criterion Eight would still be no earlier than the date of the award announcement.) For example, assume a hospital applies under Ranking Criterion Five to expand an internal medicine program by nine positions. As described in its section 5506 application, the hospital plans that expansion to occur beginning on July 1, 2012, and at that time, the hospital would add three residents, and on July 1, 2013, the hospital would add another three residents, and then on July 1, 2014, the hospital would add the last three internal medicine residents. Therefore, the effective date of three slots could be July 1, 2012, the effective date of three additional slots would be July 1, 2013, and the effective date of the last three slots would be July 1, 2014. We are interested in receiving public comments on this policy alternative. We would still propose that the effective date for proposed Ranking Criterion Eight would be no earlier than date of the award.

Thus far, we have clarified when various effective dates have been used (that is, the date of closure, or the cost reporting period following the date of the closure, or a July 1 date), and we have proposed a change to the effective date of Ranking Criteria Four through proposed Ranking Criterion Eight when

temporary cap adjustments for displaced residents were given (to be no earlier than the date of the award announcement). However, due to concerns expressed by recipients of slots under the first round of section 5506, particularly regarding the interaction with the rolling average as the retroactive section 5506 slots become effective, we are soliciting public comments on alternative approaches to implementing section 5506. While bearing in mind that section 5506(d) of the Affordable Care Act instructs the Secretary ''* * * to ensure that there is no duplication of FTE slots * * *,'' we would be interested in public comments regarding whether to either make the effective dates prospective for all section 5506 slots awarded under all ranking criteria, or, in certain instances such as when slots are awarded under Ranking Criteria One or Three, make the effective dates of the section 5506 slots seamless with the expiration of applicable temporary cap adjustments under § 413.79(h). We also are soliciting public comments on whether the regulatory temporary cap adjustment for residents displaced from closed hospitals under § 413.79(h) is still necessary and appropriate, now that there is a provision in the statute that addresses permanent reassignment of slots from closed teaching hospitals. Alternatively, we would be interested in comments regarding whether the regulatory temporary cap adjustment for displaced residents under § 413.79(h) should be preserved, but the exemption from the rolling average for those displaced FTE residents should be eliminated. These options should be considered by commenters not only in the context of section 5506 slots that have already been assigned, but also in the context of future teaching hospital closures, and how previously awarded section 5506 slots that have not as yet been filled might interact with eligibility for temporary cap adjustments for additional displaced residents in the future.

e. Clarification of Relationship Between Ranking Criteria One, Two, and Three

In the November 24, 2010 final rule with comment period, as part of the response to a comment we received requesting that the order of Ranking Criterion One (regarding an applicant hospital that assumes an entire program from a closed hospital) and Ranking Criterion Two (regarding an applicant hospital that received slots under the terms of a Medicare GME affiliation agreement from a closed hospital) be switched, we stated:

Furthermore, the commenter need not be concerned that hospitals that would fit into Ranking Criterion Two would be at a disadvantage and deprived of their fair share of slots to hospitals that would fit under Ranking Criterion One. In fact, Ranking Criteria One and Two are *not* competing with each other, and hospitals fitting into each category would get their 'fair' share of slots. For example, assume a hospital with an FTE resident cap of 100 closes. Hospital A assumes the entire programs in which 80 FTE residents were training when the hospital closed. Hospital B had been receiving 20 FTE slots from the closed hospital under the terms of a Medicare GME affiliation agreement. Hospital A applies for 80 slots under Ranking Criterion One and, all other things being equal, is awarded 80 slots. Hospital A could apply for more than 80 slots, but it could only receive consideration under Ranking Criterion One for a maximum of 80 slots. Therefore, 20 slots would remain for Hospital B to apply for and receive under Ranking Criterion Two. Accordingly, we do not believe it is necessary to reorder Ranking Criteria One and Two (75 FR 72218).

We have recently been made aware that it may not always be true that Ranking Criteria One, Two, and even Three are not competing with each other. For example, in the case where the closed hospital was training residents in excess of its FTE resident caps, it is possible for hospitals to apply under Ranking Criteria One, Two, and/or Three for more slots than are available. However, under the policy expressed in the response quoted above from the November 24, 2010 final rule with comment period, because a hospital that takes over an entire program from the closed hospital is ranked under Ranking Criterion One, and a hospital that received slots from a Medicare GME affiliation agreement from the closed hospital is ranked under Ranking Criterion Two, all the slots could be assigned to the hospital under Ranking Criterion One, leaving no slots for hospitals ranked under Ranking Criterion Two or Three. (We note that in the first round of section 5506 awards associated with hospitals that closed between March 23, 2008, and August 3, 2010, this turned out *not* to be a concern because even in the case where a closed hospital was training residents in excess of its FTE caps at the time of closure, there were no applicants for the slots that simultaneously qualified under Ranking Criteria One, Two, and/or Three). For example, a hospital that closed has an FTE resident cap of 10, but when it closed, it was training 15 FTEs in an internal medicine program. Hospital A assumes at least 90 percent of the internal medicine program; that is, the ''entire'' program (a hospital that takes on 90 percent of the residents training in a particular program at the closed hospital within 5 years prior to the hospital's closure or at the time of the hospital's closure would be deemed to have assumed an ''entire'' program (75 FR 72218)). Ninety percent of the internal medicine program is 13.5 FTEs. Because Hospital A took over the ''entire'' internal medicine program, it applies for slots under Ranking Criterion One. Hospital B applies under Ranking Criterion Three because it assumes the other 10 percent of the program, or 1.5 FTEs. However, because the closed hospital's FTE resident cap was limited to 10, it would seem that all 10 slots would be assigned to Hospital A under Ranking Criterion One, leaving no slots for Hospital B under Ranking Criterion Three. Conversely, if Ranking Criteria One and Three were ranked as equals, the 10 slots could be prorated so that both Hospital A and Hospital B each receive a ''fair'' share.

Another example might be one in which a closed hospital that was training residents in excess of its FTE resident cap of 10 ''lent'' 2 of those 10 cap slots to Hospital C under the terms of a Medicare GME affiliation agreement. Although under the terms of the Medicare GME affiliation agreement, the hospital's FTE resident cap was reduced from 10 to 8, the hospital actually trained 9 FTEs, and continued to do so until it closed. Hospital D then assumes the 9 FTEs, or the entirety of the program that remained at the closed hospital when it closed. Again, one policy approach would be to rank the ranking criteria in descending order, and assign all 10 slots to Hospital D since Hospital D qualifies under Ranking Criterion One. Alternatively, another policy approach would be to treat Ranking Criteria One and Two as equals, and then a prorata share of the 10 slots could be given each to Hospital C and Hospital D.

After consideration of these scenarios, we believe that in the case where the closed hospital was training residents in excess of its FTE resident caps, prorating among hospitals that qualify under Ranking Criteria One, Two, and Three is not warranted. This is because we believe that a hospital that assumes an entire program from the closed hospital should be ranked highest, as it has taken the boldest step to ensuring the continuity of the closed hospital's program. As we explained first in the August 3, 2010 proposed rule (75 FR 46423) and again in the November 24, 2010 final rule with comment period (75 FR 72218), ''We note that we are proposing this ranking criterion regarding affiliated hospitals as second, after the first ranking criterion regarding applying hospitals that assume an entire

program or programs from the closed hospital because, even though section 5506 of the Affordable Care Act directs the Secretary to give preference to members of the same affiliated group, we believe that a hospital that assumes the responsibility for an entire program or programs demonstrates a commitment to maintain the programs to an even greater degree than does a hospital that was affiliated with the hospital that closed and may only be maintaining a portion of the residency program or programs.'' Similarly, we believe that because section 5506 of the Affordable Care Act does give preference to members of the same affiliated group as the closed hospital, hospitals qualifying for Ranking Criterion Two should receive slots first before hospitals qualifying for slots under Ranking Criterion Three. While we would encourage a hospital to assume a part of a closed hospital's program if it does not have the capacity to assume the entire program, such a hospital would be ranked under Ranking Criterion Three, still receiving preference before all hospitals that did not necessarily have any relationship with the closed hospital and that qualify under Ranking Criteria Four and below. As we stated in the November 24, 2010 final rule with comment period (75 FR 72226), ''we would still assign the slots to hospitals qualifying under Ranking Criteria One, Two, and Three in descending order.'' Therefore, in the instance where a closed hospital is training residents in excess of its FTE resident caps when it closes, we are clarifying that we would not prorate a closed hospital's FTE resident caps among applicant hospitals that qualify under Ranking Criteria One, Two, and Three.

f. Proposed Modifications to the Section 5506 CMS Evaluation Form

We are proposing to make numerous changes to the Section 5506 CMS Evaluation Form. Most of the changes are not substantive, but are intended to clarify the requirements on the form, and therefore, we will not list them each individually. There are several proposed changes that are more substantive, and we will enumerate those. First, we are proposing to change the name of the CMS Evaluation Form to the CMS Application Form. We believe this is a more appropriate name, as it is the form used by hospitals to apply for slots under section 5506. Second, there are several instances on the proposed CMS Application Form where we prompt the applicant to specify whether the application is for a particular program, or for general cap relief, or for slots associated with a Medicare GME affiliation agreement with the closed hospital (which we did not do on the preceding form). Third, we are clarifying the titles of the Demonstrated Likelihood Criteria (DLC). Specifically, the proposed title for Demonstrated Likelihood Criterion 1 is ''Establishing a New Residency Program'', the proposed title for Demonstrated Likelihood Criterion 2 is ''Taking Over All or Part of an Existing Residency Program from the Closed Hospital, or Expanding an Existing Residency Program,'' the proposed title for Demonstrated Likelihood Criterion 3 is ''Receiving Slots for General Cap Relief,'' and the proposed title for Demonstrated Likelihood Criterion 4 is ''Receiving Slots by Virtue of Medicare GME Affiliated Group Agreement with Closed Hospital.'' Fourth, we are proposing to add a category under Demonstrated Likelihood Criterion 2 stating that if the hospital currently has unfilled positions in a residency program that have previously been approved by the ACGME, AOA, or the ABMS, and the hospital is now seeking to fill those positions, the hospital must attach documentation clearly showing its current number of approved positions, and its current number of filled positions (as proof of the unfilled positions). Fifth, we are proposing to change the wording in Ranking Criteria 4, 5, and 6, respectively, from ''The applying hospital does not meet ranking criteria 1, 2, or 3'' to ''The program does not meet ranking criterion 1, 2, or 3'' because the latter is more accurate. That is, it is possible for a hospital to qualify under Ranking Criterion 1, 2, or 3 for a particular program, and also to apply for slots separately under Ranking Criterion 4, 5, or 6 for a different program. Sixth, we are proposing to add a new Ranking Criterion 7: *The program does not meet ranking criteria 1 through 6, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.* We also are renumbering what had been the previous Ranking Criterion 7 to be the proposed Ranking Criterion 8.

Following is the proposed revised section 5506 CMS Application Form:

CMS Application Form

As Part of the Application for the Increase in a Hospital's FTE Cap(s) under Section 5506 of the Affordable Care Act: Preservation of FTE Cap Slots from Teaching Hospitals that Close

Directions: Please fill out the information below for each residency program for which the applicant hospital intends to use the increase in its FTE cap(s). If the hospital is applying for general FTE cap relief (an increase in the hospital's FTE cap(s) in recognition of already training residents in excess of the hospital's cap(s)), that application must be submitted separately from an individual program request. If the hospital is applying for slots associated with a Medicare GME affiliation agreement with a hospital that closed, that application must also be submitted separately from an individual program request.

NAME OF HOSPITAL:

MEDICARE PROVIDER NUMBER:

NAME OF MEDICARE CONTRACTOR:

CORE-BASED STATISTICAL AREA (CBSA in which the hospital is physically located—write the 5 digit code here):

COUNTY NAME (in which the hospital is physically located):

Complete the following, as applicable:

1. Name of Specialty Training Program:

2. General FTE Cap Relief:

3. Medicare GME Affiliated Group:

(Check one):

☐ Allopathic Program

☐ Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR SPECIFIC PROGRAM (OR HOSPITAL OVERALL IF SEEKING GENERAL CAP RELIEF OR SLOTS ASSOCIATED WITH A MEDICATE GME AFFILIATED GROUP) AT YOUR HOSPITAL:

Direct GME: _____ IME: _____

Section A: Demonstrated Likelihood Criteria (DLC) of Filling the FTE Slots

The applicant hospital must provide documentation to demonstrate the likelihood of filling requested slots under section 5506 within the 3 academic years immediately following the application deadline to receive slots after a particular hospital closes. *Please indicate the specific use for which you are requesting an increase in your hospital's FTE cap(s). If you are requesting an increase in the hospital's FTE cap(s) for a combination of DLC1, DLC2, or DLC3, you must complete a separate CMS Application Form for each DLC and specify the distinct*

criterion from the list below within each Form.

Demonstrated Likelihood Criterion 1: Establishing a New Residency Program

The hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both, and will establish a new residency program in the specialty. **(The hospital must check at least one of the following.)**

☐ Application for approval of the new residency program has been submitted to the ACGME, AOA or the ABMS **(The hospital must attach a copy.)**

☐ The hospital has submitted an institutional review document or program information form concerning the new program in an application for approval of the new program. **(The hospital must attach a copy.)**

☐ The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). **(The hospital must attach a copy.)**

☐ The hospital has other documentation demonstrating that it has made a commitment to start a new program **(The hospital must attach a copy.)**

Demonstrated Likelihood Criterion 2: Taking Over All or Part of an Existing Residency Program From the Closed Hospital, or Expanding an Existing Residency Program

The hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both, and a) has permanently taken over the closed hospital's entire residency program, or b) is permanently expanding its own previously established and approved residency program resulting from taking over part of a residency program from the closed hospital, or c) is permanently expanding its own existing residency program. **(The hospital must check at least one of the following.)**

☐ Application for approval to take over the closed hospital's residency program has been submitted to the ACGME, AOA, or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

☐ Application for approval of an expansion of the number of approved positions in its residency program resulting from taking over part of a residency program from the closed hospital has been submitted to the ACGME, AOA or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

☐ Application for approval of an expansion of the number of approved positions in its residency program has been submitted to the ACGME, AOA or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

☐ The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME, AOA, or the ABMS, and is now seeking to fill those positions. **(The hospital must attach documentation clearly showing its current number of approved positions, and its current number of filled positions).**

☐ The hospital has submitted an institutional review document or program information form concerning the program in an application for approval of an expansion to the program **(The hospital must attach a copy).**

Demonstrated Likelihood Criterion 3: Receiving Slots for General Cap Relief

☐ The hospital does not have sufficient room under its direct GME FTE cap or IME cap, or both, and is seeking an increase in its FTE cap(s) for general cap relief for residents that it is already training.

Demonstrated Likelihood Criterion 4: Receiving Slots by Virtue of Medicare GME Affiliated Group Agreement with Closed Hospital

☐ The hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital *received* slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, the applying hospital was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital *received* slots from the closed hospital under the terms of that affiliation agreement. **(Copies of EACH of the following must be attached.)**

- Copies of the recent Medicare GME affiliation agreement of which the applying hospital and the closed hospital were a member of before the hospital closed.
- Copies of the most recent accreditation letters for all of the hospital's training programs in which the hospital had a shared rotational arrangement (as defined at § 413.75(b)) with the closed hospital.

Section B. Level Priority Category

(Place an "X" in the appropriate box that is applicable to the level priority category that describes the applicant hospital.)

☐ First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.

☐ Second, to hospitals located in the same State as the closed hospital.

☐ Third, to hospitals located in the same region as the hospital that closed.

☐ Fourth, if the slots have not yet been fully distributed, to qualifying hospitals in accordance with the criteria established under section 5503, "Distribution of Additional Residency Positions"

Section C. Evaluation Criteria

(Place an "X" in the box for each criterion that is appropriate for the applicant hospital and for the program for which the increase in the FTE cap is requested.)

☐ Ranking Criterion One. *The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program (s) exactly as it had been operated by the hospital that closed (that is, same residents, possibly the same program director, and possibly the same (or many of the same) teaching staff).*

☐ Ranking Criterion Two. *The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare*

GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, preference would be given to an applying hospital that was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement.

☐ Ranking Criterion Three. *The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).*

☐ Ranking Criterion Four. *The program does not meet Ranking Criteria 1, 2, or 3, and the applying hospital will use additional slots to establish a new or expand an existing geriatrics residency program.*

☐ Ranking Criterion Five: *The program does not meet Ranking Criteria 1 through 4, the applying hospital is located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

☐ Ranking Criterion Six: *The program does not meet Ranking Criteria 1 through 5, and the applying hospital is not located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

☐ Ranking Criterion Seven: *The program does not meet Ranking Criteria 1 through 6, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.*

☐ Ranking Criterion Eight: *The applying hospital seeks the slots for purposes that do not fit into any of the above ranking criteria.*

Application Process and CMS Central Office and Regional Office Mailing Addresses for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. The following information must be submitted on applications to receive an increase in FTE resident caps:

- The name and Medicare provider number, and Medicare contractor (to which the hospital submits its cost report) of the hospital.
- The total number of requested FTE resident slots for direct GME or IME, or both.
- A completed copy of the CMS Application Form for each residency program for which the hospital intends to use the requested increase in FTE residents.
- Source documentation to support the assertions made by the hospital on the CMS Application Form.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (If the CMS Form 2552–96 is applicable, include copies of Worksheets E, Part A, E–3, Part IV, and if a hospital received an increase to its FTE cap(s) under section 422 of the MMA, a copy of E–3, Part VI. If the CMS Form 2552–10 is applicable, include copies of Worksheets E, Part A, and E–4).
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information:

''I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.''

J. Proposed Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51697), we finalized our policy for reporting costs of qualified defined benefit pension plans for Medicare cost-finding purposes. Specifically, beginning with cost reporting periods on or after October 1, 2011, a provider's pension cost for cost-finding purposes equals the cash basis contribution deposits plus any carry forward contributions, subject to a limitation. Providers with current contributions and carry forward contributions in excess of the limit may request approval of excess contributions, which will be reviewed on a case-by-case basis. Some or all of the excess contributions will be approved, as applicable, if it is determined that all or a portion of the excess contribution(s) are reasonable and necessary. To the extent that approval is granted, that portion of the excess is allowable as current period pension costs. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for full details on this policy.

In addition to finalizing this new policy in the FY 2012 IPPS/LTCH PPS final rule, we stated that we intended to make future amendments to conform existing regulations to this final policy (76 FR 51693). The existing regulations at 42 CFR 413.24 and 413.100 specify that pension costs of qualified defined benefit plans are reported on an accrual basis of accounting method. Sections 413.24 and 413.100 provide that revenue is reported in the period in which it is earned, regardless of when it is collected and expenses are reported in the period in which they are incurred, regardless of when it is paid. For Medicare payment purposes, the costs are generally allowable in the year in which the costs are accrued and claimed, subject to specific exceptions. Furthermore, for accrued costs to be recognized for Medicare payment in the year of the accrual, the requirements must be met with respect to the liquidation of related liabilities. Therefore, to conform these two existing regulations to the final policy we adopted in the FY 2012 IPPS/LTCH PPS final rule with regard to pension costs for Medicare cost-finding purposes, we are proposing to amend the general cost reporting rules under §§ 413.24 and 413.100 to note the exception for recognizing actual pension contributions funded during the cost reporting period on a cash basis. We also plan to revise section 2305.2 of the Provider Reimbursement Manual to reflect this policy change.

K. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing ''rural community hospitals'' to furnish covered inpatient hospital services to Medicare

beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost report years beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and converted to CAH status. This left nine hospitals participating at that time. In 2008, we announced a solicitation for up to six additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These four additional hospitals began under the demonstration payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left 7 of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008), participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, which established the rural community hospital demonstration program. Sections 3123 and 10313 of the Affordable Care Act changed the rural community hospital demonstration program in several ways. First, the Secretary is required to conduct the demonstration program for an additional 5-year period that begins on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act requires, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Secretary to provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation (section 410A(g)(4)(A) of Pub. L. 108–173, as added by section 3123(a) of the Affordable Care Act and further amended by section 10313 of such Act). In addition, the Affordable Care Act provides that, during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20 (section 410A(g)(2) of Public Law 108–173, as added by section 3123(a) and amended by section 10313 of the Affordable Care Act). Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States under section 410A(a)(2) of Public Law 108–173 for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period (section 410A(g)(3) of Pub. L. 108–173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such Act).

We published a solicitation for applications for additional participants in the rural community hospital demonstration program in the Federal Register on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density that are eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost report periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008 and that are still participating, the new selection led to a total of 23 hospitals in the demonstration.

In addition, section 410A(c)(2) of Public Law 108–173 required that, ''[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.'' This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral in its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or

yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality. Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals.

In the past eight IPPS final regulations, spanning the period for which the demonstration program has been implemented, we have adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. As we discussed in the FYs 2005 through 2012 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, and 76 FR 51698, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner. In light of the statute's budget neutrality requirement, we are proposing a methodology to calculate a budget neutrality adjustment factor to the FY 2013 national IPPS rates.

In general terms, in each of these previous years, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. We used finalized, or settled, cost reports, as available, and ''as submitted'' cost reports for hospitals for which finalized cost reports were not available. Annual market basket percentage increase amounts provided by the CMS Office of the Actuary reflecting the growth in the prices of inputs for inpatient hospitals were applied to these cost amounts. An annual update factor provided by the CMS Office of the Actuary reflecting growth in the volume of inpatient operating services was also applied. For the budget neutrality calculations in the IPPS final rules for FYs 2005 through 2011, the annual volume adjustment applied was 2 percent; for the IPPS final rule for FY 2012, it was 3 percent. For a detailed discussion of our budget neutrality offset calculations, we refer readers to the IPPS final rule applicable to the fiscal year involved.

In general, for FYs 2005 through 2009, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Public Law 108–173. (The reasonable cost-based methodology authorized by section 410A of Pub. L. 108–173, and as later amended by Pub. L. 111–148, as applicable to the year, is hereafter referred to as the ''reasonable cost methodology.'' We refer readers to section 410A(b) and (g)(4) of Pub. L. 108–173 and Pub. L. 111–148.) (We ascertained the estimated amount that would be paid in an earlier given year under the reasonable cost methodology and the estimated amount that would otherwise be paid without the demonstration in an earlier given year from ''as submitted'' cost reports that were submitted by the hospitals prior to the inception of the demonstration.) We then updated the estimated cost described above to the current year by multiplying it by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustments. For the FY 2010 IPPS final rule, data from finalized cost reports reflecting the participating hospitals' experience under the demonstration were available. Specifically, the finalized cost reports for the first 2 years of the demonstration, that is, cost reports for cost reporting years beginning in FYs 2005 and 2006 (CYs 2004, 2005, and 2006) were available. These data showed that the actual costs of the demonstration for these years exceeded the amounts originally estimated in the respective final rules for the budget neutrality adjustment. In the FY 2010 IPPS/LTCH PPS final rule, we included in the budget neutrality offset amount an amount in addition to the estimate of the demonstration costs in that fiscal year. This additional amount was based on the amount that the costs of the demonstration for FYs 2005 and 2006 exceeded the budget neutrality offset amounts finalized in the IPPS rules applicable for those years.

Following upon the FY 2010 IPPS/LTCH PPS final rule, we have continued to propose a methodology for calculating the budget neutrality offset amount to account for both the estimated demonstration costs in the upcoming fiscal year and an amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we note that on account of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we have been unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in a given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007. (For only a small fraction of the hospitals that have participated in the demonstration from FY 2007 to FY 2010 have cost reports been finalized in any year, making the overall calculation of this component of the budget neutrality impossible at this time for any given year.)

2. Proposed FY 2013 Budget Neutrality Offset Amount

We revisited the issue of which cost reports to propose to use for calculating the FY 2013 budget neutrality offset amount. Although we used finalized cost reports where available for the FYs 2010, 2011, and 2012 IPPS/LTCH PPS final rules, for FY 2013, we are proposing to use the ''as submitted'' cost report for each hospital participating in the demonstration for the cost report period ending in CY 2010 in estimating the costs of the demonstration. We believe a way to streamline our methodology for calculating the budget neutrality offset amount would be to use cost reports all with the same status (that is, only ''as submitted'' cost reports as opposed to a mix of ''as submitted'' and ''settled'' cost reports) from the same time period for all hospitals participating in the demonstration (as opposed to varying cost reports of statuses from varying years for the various hospitals as has been done previously). Therefore, because ''as submitted'' cost reports ending in CY 2010 are the most recent complete set of cost reports for all demonstration hospitals, we are proposing to use these cost reports for our budget neutrality offset estimate. Further, because ''as submitted'' cost reports ending in CY 2010 are recent available cost reports, we believe they would be an accurate predictor of the costs of the

demonstration in FY 2013 because they give us a recent picture of the participating hospitals' costs.

In revisiting the issue of which data sets to propose to use in the budget neutrality offset amount calculation, we also revisited the methodology for calculating the budget neutrality offset amount. In this proposed rule, we are proposing changes to that methodology in an effort to further improve and refine it. We note that the proposed methodology varies, in part, from that finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51698 through 51707). Specifically, in proposing refinements to the methodology, we would simplify the calculation so that it includes only a few steps. In addition, we are proposing to incorporate different update factors (the market basket percentage increase and the applicable percentage increase, as applicable, to several years of data as opposed to solely using the market basket percentage increase) for the calculation of the budget neutrality offset amount. As explained in greater detail below, we believe this approach would maximize the precision of our calculation because we believe it would more closely replicate payments made with and without the demonstration.

We note that, although we are proposing changes to certain aspects of the budget neutrality offset amount calculation, several core components of the methodology would remain unchanged. For example, we are continuing to propose to include in the budget neutrality offset amount the estimate of the demonstration costs for the upcoming fiscal year and the amount by which the actual demonstration costs corresponding to an earlier given year (which would be known once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule).

The proposed methodology for calculating the estimated FY 2013 demonstration cost for the 23 currently participating hospitals is as follows:

Step 1: For each of the 23 participating hospitals, we are proposing to identify the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for the hospital's cost reporting period ending in CY 2010) in FY 2010. The general reasonable cost amount calculated under the reasonable cost methodology for any applicable year is hereafter referred to as the ''reasonable cost amount.''

Because section 410A of Public Law 108–173 stipulates swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we also are proposing to include the cost of these services, as reported on the cost reports for the hospitals that provide swing-bed services, within the general total estimated FY 2010 reasonable cost amount for covered inpatient hospitals services under the demonstration. As indicated above, we are proposing to use ''as submitted'' cost reports for the hospital's cost reporting period ending in CY 2010 for this calculation.

We are proposing to sum the two above-referenced amounts to calculate the general total estimated FY 2010 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to multiply this sum (that is, the general total estimated FY 2010 reasonable cost amount for covered inpatient hospital services for all 23 hospitals) by the FYs 2011 through 2013 IPPS market basket percentage increases, which were formulated by the CMS Office of the Actuary. In this proposed rule, the current estimate of the FY 2013 IPPS market basket percentage increase provided by the CMS Office of the Actuary is indicated in section IV.H.1. of this preamble.) We also are proposing to then multiply the product of the general total estimated FY 2010 reasonable cost amount for all 23 hospitals and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for the years 2011 through 2013—the result would be the general total estimated FY 2013 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to apply the IPPS market basket percentage increases applicable for FYs 2011 through 2013 to the FY 2010 reasonable cost amount described above to model the estimated FY 2013 reasonable cost amount under the demonstration. We are proposing to use the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved. The 3-percent annual volume adjustment was stipulated last year by the CMS Office of the Actuary and is proposed because it is intended to accurately reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledge the possibility that inpatient caseloads for small hospitals may fluctuate, and are proposing to incorporate into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the 23 hospitals, we are proposing to identify the general estimated amount that would otherwise be paid in FY 2010 under applicable Medicare payment methodologies for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2010) if the demonstration was not implemented. Similarly, as in Step 1, for the hospitals that provide swing-bed services, we are proposing to identify the estimated amount that generally would otherwise be paid for these services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2010) and include it in the total FY 2010 general estimated amount that would otherwise be paid for covered inpatient hospital services without the demonstration. We are proposing to sum these two amounts in order to calculate the estimated FY 2010 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration.

We are proposing to multiply the above amount (that is, the estimated FY 2010 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration) by the FYs 2011 through 2013 IPPS applicable percentage increases and the proposed 3 percent annual volume adjustment for FYs 2011 through 2013—the result would be the general total estimated FY 2013 costs that would be paid without the demonstration for covered inpatient hospital services to the 23 participating hospitals. In this proposed rule, the current estimate of the FY 2013 IPPS applicable percentage increase is 2.1 percent. This methodology differs from Step 1, in which we are proposing to apply the market basket percentage increases to the sum of the hospitals' general total FY 2010 estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments would constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Hospitals participating in the demonstration would be participating under the IPPS payment methodology if they were not in the demonstration. We note that such use of the applicable percentage increase would represent a shift from formulations in previous years of the budget neutrality offset amount. In this FY 2013 proposed rule, we are trying to increase the precision of the different nature of the projections that we are proposing for estimating the reasonable cost amounts and the estimated payments that would otherwise be paid without the demonstration.

Step 3: We are proposing to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the 23 hospitals for covered inpatient hospital services for FY 2013 if the demonstration was not implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all 23 hospitals for covered inpatient hospital services for FY 2013). We are proposing that the resulting difference would be the amount for which an adjustment to the national IPPS rates would be calculated.

For this proposed rule, the resulting difference is $35,077,708. For this FY 2013 IPPS/LTCH PPS proposed rule, this amount is the estimated amount for which an adjustment to the national IPPS rates is being calculated. This estimated amount is based on the specific assumptions identified regarding the data sources that are used, that is, ''as submitted'' recently available cost reports. We note that if updated data become available prior to the FY 2013 final rule, we are proposing to use them to the extent appropriate to estimate the costs of the demonstration program in FY 2013. Therefore, this estimated budget neutrality offset amount may change in the final rule depending on the availability of updated data. Similar to previous years, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FY 2007, 2008, 2009, or 2010) are available prior to the FY 2013 IPPS/LTCH PPS final rule, we will include in the budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. (The final settled costs of the demonstration for a year would be calculated by subtracting the total amount that would otherwise be paid under the applicable Medicare payment systems without the demonstration for the year from the amount paid to those hospitals under the reasonable cost methodology for such year.)

L. Hospital Routine Services Furnished Under Arrangements

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we included a provision that limits the circumstances under which a hospital may furnish services to Medicare beneficiaries ''under arrangement.'' Under the revised policy, therapeutic and diagnostic services are the only services that may be furnished under arrangements outside of the hospital to Medicare beneficiaries. ''Routine services'' (that is, bed, board, and nursing and other related services) must be furnished by the hospital. Under this revised policy, routine services furnished to Medicare beneficiaries as inpatients of the hospital are considered services furnished by the hospital. If these services are furnished outside of the hospital, the services are considered to be furnished ''under arrangement.''

We have become aware that a number of affected hospitals need additional time to restructure existing arrangements and establish necessary operational protocols to comply with the requirement that therapeutic and diagnostic services are the only services that may be furnished outside of the hospital to Medicare beneficiaries ''under arrangement,'' and that ''routine services'' must be furnished by the hospital. While we still believe that our policy is correct and consistent with the statutory language, we also believe that because a number of hospitals are actively pursuing compliance (often building construction or restructuring is involved), it is appropriate to postpone the effective date of this requirement to give hospitals additional time to comply with the provision.

Therefore, we are proposing to change the implementation date of this requirement to be effective for cost reporting periods beginning on or after October 1, 2013. We expect that, during FY 2013, hospitals will complete the work needed to ensure compliance with the new requirement. Beginning with a hospital's FY 2014 cost reporting period, we expect that all hospitals would be in full compliance with the revised policy for services furnished under arrangement. We will continue to work with affected hospitals to communicate the requirement established by this provision, and to provide continued guidance regarding compliance with the provision.

M. Proposed Technical Change

In an interim final rule that appeared in the November 27, 2007 **Federal Register** (72 FR 66895 through 66897), we made changes to the regulations governing the application of the emergency Medicare GME affiliation agreement rules in order to address the needs of hospitals located in the section 1135 emergency area in the aftermath of Hurricane Katrina and Rita. In that rule, we changed the length of emergency affiliation agreements from 3 years to 5 years under 42 CFR 413.79(f)(7) (then § 413.79(f)(6)); that is, we specified that the emergency Medicare GME affiliation agreement must terminate no later than the conclusion of 4 academic years following the academic year during which the section 1135 emergency period began. However, we inadvertently did not make a conforming change to 42 CFR 413.79(f)(7)(i)(B). We are proposing to change the regulatory text specified § 413.79(f)(7)(i)(B) to make it consistent with the regulatory text under § 413.79(f)(7).

V. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services ''in accordance with a prospective payment system established by the Secretary.'' Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. The IPPS for capital-related costs was initially implemented in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to

determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in § 412.312 of the regulations. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at § 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under §§ 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, as noted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725 and 51804), FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Finally, under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS a new hospital is paid 85 percent of its Medicare allowable capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Hospitals Located in Puerto Rico

Section 412.374 of the regulations provides for the use of a blended payment amount for prospective payments for capital-related costs to hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate. Capital IPPS payments to hospitals located in Puerto Rico are computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. For additional details on capital IPPS payments to hospitals located in Puerto Rico, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

C. Proposed Changes in the Documentation and Coding Adjustment for FY 2013

1. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we established adjustments to both the national operating standardized amount and the national capital Federal rate to eliminate the estimated effect of changes in documentation and coding resulting from the adoption of the MS–DRGs that do not reflect real changes in case-mix. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010. However, to comply with section 7(a) of Public Law 110–90, enacted on September 29, 2007, in a final rule published in the **Federal Register** on November 27, 2007 (72 FR 66886 through 66888), we modified the documentation and coding adjustment for FY 2008 to −0.6 percent, and consequently revised the FY 2008 IPPS operating and capital payment rates, factors, and thresholds accordingly, with these revisions effective October 1, 2007.

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent instead of the −1.8 percent adjustment established in the FY 2008 IPPS final rule with comment period. As discussed in the FY 2009 IPPS final rule with comment period (73 FR 48447 and 48733 through 48774), we applied an additional documentation and coding adjustment of −0.9 percent to the FY 2009 IPPS national standardized amounts and the national capital Federal rate. The documentation and coding adjustments established in the FY 2009 IPPS final rule, as amended by Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment in FY 2009 was in addition to the −0.6 percent adjustment in FY 2008, yielding a combined effect of −1.5 percent. (For additional details on the development and implementation of the documentation and coding adjustments for FY 2008 and FY 2009, we refer readers to section II.D. of this preamble and the following rules published in the **Federal Register:** August 22, 2007 (72 FR 47175 through 47186 and 47431 through 47432); November 27, 2007 (72 FR 66886 through 66888); and August 19, 2008 (73 FR 48447 through 48450 and 48773 through 48775).)

For the FY 2011 IPPS/LTCH PPS proposed and final rules, we performed a retrospective evaluation of the FY 2009 claims data updated through December 2009 using the same analysis methodology as we did for FY 2008 claims in the FY 2010 IPPS/RY 2010 LTCH PPS proposed and final rules. Based on this evaluation, our actuaries determined that the implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355), we implemented an additional adjustment to the FY 2011 national capital Federal rate of −2.9 percent to account for part of the effect of the estimated changes in documentation and coding changes under the MS–DRG system that occurred in FYs 2008 and 2009 that did not reflect real changes in case-mix. Consistent with past practice, this −2.9 percent adjustment was applied in a cumulative manner, which yielded a combined effect of −4.4 percent. (For additional information on our estimate of the 5.4 percent cumulative documentation effect under the MS–DRG system for FYs 2008 and 2009 and the additional −2.9 percent documentation and coding adjustment applied to the national capital Federal rate in FY 2011, we refer readers to the

FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24014) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355)).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51727), we made an additional −1.0 percent adjustment to the national capital Federal rate to account for the remainder of the 5.4 percent estimate of the cumulative effect of documentation and coding changes under the MS–DRG system that occurred during FYs 2008 and 2009. Consistent with past practice, this −1.0 percent adjustment was applied in a cumulative manner, which yielded a combined effect of −5.4 percent.

2. Prospective Documentation and Coding Adjustment to the National Capital Federal Rate for FY 2013 and Subsequent Years

We continue to believe that it is appropriate to make adjustments to the capital IPPS rates to eliminate the effect of any documentation and coding changes as a result of the implementation of the MS–DRGs. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as payments that otherwise would have been made in those years absent the change to the MS–DRGs. Under section 1886(g) of the Act, the Secretary has broad authority in establishing and implementing the IPPS for acute-care hospital inpatient capital-related costs (that is, the capital IPPS). We have consistently stated since the initial implementation of the MS–DRG system that we do not believe it is appropriate for Medicare expenditures under the capital IPPS to increase due to MS–DRG related changes in documentation and coding. Accordingly, we believe that it is appropriate under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110–90, to make adjustments to the national capital Federal rate to eliminate the full effect of the documentation and coding changes resulting from the adoption of the MS–DRGs. We believe that this is appropriate because, in absence of such adjustments, the effect of the documentation and coding changes resulting from the adoption of the MS–DRGs results in inappropriately high capital IPPS payments because that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs).

As noted above, based on our retrospective evaluation of the FY 2009 claims, our actuaries determined that implementation of the MS–DRG system resulted in a 5.4 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2009. To date, we have made adjustments to the national capital Federal rate to account for the estimated 5.4 percent documentation and coding effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009 (that is, −0.6 percent in FY 2008, −0.9 percent in FY 2009, −2.9 percent in FY 2011, and −1.0 in FY 2012).

As discussed in greater detail in section II.D.10. of this preamble, we believe it is appropriate to analyze claims data from FY 2010 to determine whether any additional adjustment would be required to ensure that the adoption of MS–DRGs was implemented in a budget neutral manner. Specifically, for this proposed rule, we analyzed FY 2010 data on claims paid through December 2011 using our existing methodology (as described in section II.D.4. of this preamble). Based on this analysis, our actuaries determined that implementation of the MS–DRG system resulted in a 6.2 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2010. This is an estimated additional 0.8 percentage point increase over the 5.4 percent reduction currently applied to the national capital Federal rate.

Therefore, in this proposed rule, under the Secretary's broad authority under section 1886(g) of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act, and consistent with our proposal for the operating IPPS standardized amounts (discussed in section II.D.5. of this preamble), we are proposing to reduce the national capital Federal rate in FY 2013 by an additional 0.8 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system that did not reflect an increase in case-mix severity in FY 2010. Furthermore, consistent with the documentation and coding adjustments we have made in the past, we are proposing to leave the proposed −0.8 percent adjustment in place for FY 2013 and subsequent fiscal years to account for the effect those years. As explained above, this proposed −0.8 percent adjustment accounts for the remainder of our current estimate of the cumulative effect of documentation and coding changes under the MS–DRG system that occurred during FYs 2008, 2009, and 2010 of 6.2 percent minus the existing cumulative adjustment already applied to the national capital Federal rate of −5.4 percent. We note that this proposed adjustment only adjusts the national capital Federal rate prospectively. It does not attempt to recoup any excess payments that have resulted in FYs 2010, 2011, and 2012 as a result of this additional effect of documentation and coding in those years.

3. Documentation and Coding Adjustment to the Puerto Rico-Specific Capital Rate

Under § 412.74, Puerto Rico hospitals are currently paid based on 75 percent of the national capital Federal rate and 25 percent of the Puerto Rico-specific capital rate. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50358 through 50359), we discussed the retrospective evaluation of the FY 2009 claims data from the March 2010 update of the MedPAR file of hospitals located in Puerto Rico using the same methodology used to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals. This analysis shows that the change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico was approximately 2.6 percent. We also explained that we continue to believe that an adjustment for such increases is appropriate because all hospitals have the same financial incentives for documentation and coding improvements, and the same ability to benefit from the resulting increase in aggregate payments that do not reflect real changes in case-mix.

Given this case-mix increase due to changes in documentation and coding under the MS–DRGs, under the Secretary's broad authority under section 1886(g) of the Act, we established an adjustment to the Puerto Rico-specific capital rate of −2.6 percent in FY 2011 for the cumulative increase in case-mix due to changes in documentation and coding under the MS–DRGs for FYs 2008 and 2009. In addition, consistent with our implementation of other prospective MS–DRG documentation and coding adjustments to the capital Federal rate and operating IPPS standardized amounts, we established that the −2.6 percent adjustment will remain in place for subsequent fiscal years in order to ensure that changes in documentation and coding resulting from the adoption of the MS–DRGs do not lead to an increase in aggregate payments not reflective of an increase in real case-mix in subsequent years. Therefore, the −2.6 percent adjustment to the capital

Puerto Rico-specific rate made in FY 2011 reflects the entire amount of our estimate at that time of the effects of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008 and 2009 from hospitals located in Puerto Rico.

As discussed above, for this proposed rule, we analyzed FY 2010 data on claims paid through December 2011 using our existing methodology to determine if any additional adjustment for the effects of documentation and coding that did not reflect real changes in case-mix is warranted. Based on this analysis (which is described in greater detail in section II.D.10. of this preamble), we found no significant additional effect of documentation and coding that would warrant any additional adjustment. Therefore, we are not proposing any additional adjustment to the capital Puerto Rico-specific rate for FY 2013 for the effect of documentation and coding that did not reflect real changes in case-mix.

D. Proposed Changes for Annual Update for FY 2013

The annual update to the capital IPPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), proposed for FY 2013 is discussed in section III. of the Addendum to this proposed rule.

VI. Proposed Changes for Hospitals Excluded From the IPPS

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount was multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and IPPS-excluded cancer hospitals.

Payment to children's hospitals and cancer hospitals that are excluded from the IPPS continues to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a) of the regulations, RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

We are proposing that the FY 2013 rate-of-increase percentage to be applied to the target amount for cancer and children's hospitals and RNHCIs would be the FY 2013 percentage increase in the IPPS operating market basket. For this proposed rule, the FY 2013 percentage increase in the IPPS operating market basket is currently estimated to be 3.0 percent. Beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's and cancer hospitals. As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), with IRFs, IPFs, and LTCHs being paid under their own PPS, the remaining number of providers being paid based on reasonable cost subject to a ceiling (that is, children's hospitals, 11 cancer hospitals, and RNHCIs) is too small and the cost report data are too limited to be able to create a market basket solely for these hospitals. For FY 2013, we are proposing to continue to use the IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for the reasons discussed in the FY 2006 IPPS final rule.

We are proposing to use the FY 2006-based IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for FY 2013. Therefore, based on IHS Global Insight, Inc.'s 2012 first quarter forecast, with historical data through the 2011 fourth quarter, the current estimate of the IPPS operating market basket update for FY 2013 is 3.0 percent (that is, the estimate of the market basket rate-of-increase). We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2013.

We note that IRFs, IPFs, and LTCHs, which were paid previously under the reasonable cost methodology, now receive payment under their own prospective payment systems, in accordance with changes made to the statute. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provided transition periods of varying lengths during which time a portion of the prospective payment was based on cost-based reimbursement rules under Part 413. (However, certain providers do not receive a transition period or may elect to bypass the transition period as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that the various transition periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IV. of the Addendum to this proposed rule for the specific proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2013. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2013

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Social Security Act (the Act), effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as ''a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.'' Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (LOS) (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by a LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR Part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in section VIII. of this preamble, when we refer to discharges, the intent is to describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA System to payments under the LTCH PPS. During this 5-year transition period, a LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts. However, effective for cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, Subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51743) for a chronological summary of the main legislative and regulatory developments affecting the LTCH PPS through the annual update cycles prior to this FY 2013 rulemaking cycle.

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

Under the existing regulations at §§ 412.23(e)(1) and (e)(2)(i), which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare and must have an average Medicare inpatient LOS of greater than 25 days. Alternatively, § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c), and therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). In the RY 2005 LTCH PPS final rule (69 FR 25676), we clarified that the discussion of beneficiary liability in the August 30, 2002 final rule was not meant to establish rates or payments for, or define Medicare-eligible expenses. Under § 412.507, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, as consistent with other established hospital prospective payment systems, a LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services as specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. Therefore, if the Medicare payment was for a SSO case (§ 412.529) that was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH could also charge the beneficiary for services delivered on those uncovered days (§ 412.507).

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health

Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services ''for which a claim is submitted other than in an electronic form specified by the Secretary.'' Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial ''in such unusual cases as the Secretary finds appropriate'' (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified as 45 CFR parts 160 and 162, Subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2013

1. Background

Section 123 of the BBRA requires that the Secretary implement a PPS for LTCHs (that is, a per discharge system with a diagnosis-related group (DRG)-based patient classification system reflecting the differences in patient resources and costs). Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine ''the feasibility and the impact of basing payment under such a system [the long-term care hospital (LTCH) PPS] on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients, as well as the use of the most recently available hospital discharge data.''

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system (that is, the CMS DRGs) that was utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect ''the differences in patient resource use * * *.'' of LTCH patients (section 123(a)(1) of the BBRA (Pub. L. 106–113)).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development and implementation and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR Part 412, Subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. As described in section II.G. of this preamble, for FY 2013, we are not proposing to create or delete any MS–DRGs, and as such we would continue to have a total of 751 MS–DRG groupings for FY 2013. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In a departure from the IPPS, and as discussed in greater detail below in section VII.B.3.f. of this preamble, we are proposing to continue to use low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 LTCH cases) in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. For purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we are proposing to group all of the low-volume MS–LTC–DRGs into five quintiles based on average charge per discharge. (A detailed discussion of the initial development and application of the quintile methodology appears in the August 30, 2002 LTCH PPS final rule (67 FR 55978).) Consistent with our existing methodology, we also are proposing to account for adjustments to payments for SSO cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG). Furthermore, we are proposing to continue to make adjustments to account for nonmonotonically increasing weights, when necessary. That is, theoretically, cases under the MS–LTC–DRG system that are more severe require greater expenditure of medical care resources and will result in higher average charges such that, in the severity levels within a base MS–LTC–DRG, the weights should increase monotonically with severity from the lowest to highest severity level. (We discuss nonmonotonicity in greater detail and our methodology to adjust the MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights in section VII.B.3.g. (Step 6) of this preamble.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted above in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The

GROUPER software program does not recognize all ICD–9–CM procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKG), or minor surgical procedures (for example, biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS–LTC–DRG to which a beneficiary's stay is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Through FY 2010, the number of secondary or additional diagnoses and the number of surgical procedures considered for MS–DRG assignment was limited to nine and six, respectively. However, for claims submitted on the 5010 format beginning January 1, 2011, we increased the capacity to process diagnosis and procedure codes up to 25 diagnoses and 25 procedures. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. We refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule for a complete discussion of this change (75 FR 50127).

Upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). HIPAA Transactions and Code Sets Standards regulations at 45 CFR parts 160 and 162 require that no later than October 16, 2003, all covered entities must comply with the applicable requirements of Subparts A and I through R of Part 162. Among other requirements, those provisions direct covered entities to use the ASC X12N 837 Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, and the applicable standard medical data code sets for the institutional health care claim or equivalent encounter information transaction (45 CFR 162.1002 and 45 CFR 162.1102). For additional information on the ICD–9–CM Coding System, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47241 through 47243 and 47277 through 47281). We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002 LTCH PPS final rule (67 FR 55981 through 55983). Additional coding instructions and examples are published in the *Coding Clinic for ICD–9–CM,* a product of the American Hospital Association. (We refer readers to section II.G.13. of this preamble for additional information on the annual revisions to the ICD–9–CM codes.)

With respect to the ICD–9–CM coding system, we have been discussing the conversion to the ICD–10–CM and the ICD–10–PCS coding systems for many years. In prior rules published in the **Federal Register** (for example, section II.G.11. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50128)), we discussed the implementation date for the conversion to the ICD–10–CM and ICD–10–PCS coding systems. We refer readers to section II.G.9. of this preamble for additional information on the adoption of the ICD–10–CM and ICD–10–PCS systems.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), individual DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication and comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare contractors (that is, fiscal intermediaries and MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the Medicare contractor and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2013

As specified by our regulations at § 412.517(a), which requires that the MS–LTC–DRG classifications and relative weights be updated annually and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2012, through September 30, 2013 (FY 2013) consistent with the changes to specific MS–DRG classifications presented in section II.G. of this preamble (that is, proposed GROUPER Version 30.0). Therefore, the proposed MS–LTC–DRGs for FY 2013 presented in this proposed rule are the same as the proposed MS–DRGs that are being proposed for use under the IPPS for FY 2013. In addition, because the proposed MS–LTC–DRGs for FY 2013 are the same as the proposed MS–DRGs for FY 2013, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed Version 30.0 of the GROUPER discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and proposed changes to the ICD–9–CM coding system, also would be applicable under the LTCH PPS for FY 2013.

3. Development of the Proposed FY 2013 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR 55984), one of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case.

Although the adoption of the MS–LTC–DRGs resulted in some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, the basic methodology for developing the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule continues to be determined in accordance with the general methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). (For additional details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculated a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in a MS–LTC–DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2013

Beginning with the FY 2008 update, we established a budget neutrality requirement for the annual update to the MS–LTC–DRG classifications and relative weights at § 412.517(b) (in conjunction with § 412.503), such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the classification and relative weight changes (72 FR 26882 through 26884). Consistent with § 412.517(b), we are proposing to continue to apply our established two-step budget neutrality methodology, which is based on the current year MS–LTC–DRG classifications and relative weights. (For additional information on the established two-step budget neutrality methodology, we refer readers to the FY 2008 IPPS final rule (72 FR 47295 through 47296).) Thus, for this proposed rule, the proposed annual update to the MS–LTC–DRG classifications and relative weights for FY 2013 are based on the FY 2012 MS–LTC–DRG classifications and relative weights established in Table 11 listed in section VI. of the Addendum to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51813).

c. Data

In this proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2013, we are proposing to obtain total charges from FY 2011 Medicare LTCH bill data from the December 2011 update of the FY 2011 MedPAR file, which are the best available data at this time, and to use the proposed Version 30.0 of the GROUPER to classify LTCH cases. Consistent with our existing methodology, we also are proposing that if more recent data become available, we would use those data and the finalized Version 30.0 of the GROUPER in establishing the FY 2013 MS–LTC–DRG relative weights in the final rule.

Consistent with our historical methodology, we are proposing to exclude the data from LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. Furthermore, consistent with our historical practice, we are proposing to continue to exclude Medicare Advantage (Part C) claims, which are now included in the MedPAR files, in the calculations for the relative weights under the LTCH PPS that are used to determine payments for Medicare fee-for-service claims. Specifically, under this proposal, we are not using any claims from the MedPAR files that have a GHO Paid indicator value of ''1,'' which effectively removes Medicare Advantage claims from the relative weight calculations (73 FR 48532). Accordingly, in the development of the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule, we are proposing to exclude the data of 14 all-inclusive rate providers and the 2 LTCHs that are paid in accordance with demonstration projects that had claims in the December 2011 update of the FY 2011 MedPAR file, as well as any Medicare Advantage claims.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients and treatment of infections and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2013. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this proposed methodology, we reduce the impact of the variation in charges across providers on any particular proposed MS–LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each case to hospital-specific relative charge values and then adjust those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with our established methodology, under this proposal, we would continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. (Step 3) of this preamble) by the average adjusted charge for all cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case (67 FR 55989).

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at a LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case at a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Proposed Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of DRGs based on volume of cases within specific MS–LTC–DRGs. MS–LTC–DRGs with at least 25 cases are each assigned a unique relative weight; low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 cases based on a given year's claims data) are grouped into quintiles (as described below) and assigned the relative weight of the quintile. No-volume MS–LTC–DRGs (that is, no cases in the given year's claims data are assigned to those MS–LTC–DRGs) are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). In this proposed rule, we are proposing to continue to utilize these same three categories of MS–LTC–DRGs for purposes of the treatment of severity levels in determining the proposed MS–LTC–DRG relative weights for FY 2013. (We provide in-depth discussions of our policy regarding weight-setting for proposed low-volume MS–LTC–DRGs in section VII.B.3.f. of the preamble of this proposed rule and for proposed no-volume MS–LTC–DRGs, under Step 5 in section VII.B.3.g. of this preamble.)

As also noted above, while the LTCH PPS and the IPPS use the same patient classification system, the methodology that is used to set the DRG relative weights for use in each payment system differs because the overall volume of cases in the LTCH PPS is much less than in the IPPS. In general, consistent with our existing methodology we are proposing to use the following steps to determine the proposed FY 2013 MS–LTC–DRG relative weights: (1) if a proposed MS–LTC–DRG has at least 25 cases, it is assigned its own proposed relative weight; (2) if a proposed MS–LTC–DRG has between 1 and 24 cases, it is assigned to a quintile for which we compute a proposed relative weight for all of the proposed MS–LTC–DRGs assigned to that quintile; and (3) if a proposed MS–LTC–DRG has no cases, it is cross-walked to another proposed MS–LTC–DRG based upon clinical similarities to assign an appropriate proposed relative weight (as described below in detail in Step 5 of section VII.B.3.g. of this preamble). Furthermore, in determining the proposed FY 2013 MS–LTC–DRG relative weights, when necessary, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail below in Step 6 of section VII.B.3.g. of this preamble. We refer readers to the discussion in the FY 2010 IPPS/RY LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), consistent with our existing methodology, for purposes of determining the proposed FY 2013 MS–LTC–DRG relative weights, we are proposing to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we group the proposed ''low-volume MS–LTC–DRGs'' (that is, proposed MS–LTC–DRGs that contained between 1 and 24 cases annually) into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995 and 72 FR 47283 through 47288). In determining the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule, in cases where the initial assignment of a proposed low-volume MS–LTC–DRG to quintiles resulted in nonmonotonicity within a base-DRG, in order to ensure appropriate Medicare payments, consistent with our historical methodology, we are proposing to make adjustments to the treatment of proposed low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail below in section VII.B.3.g. (Step 6) in this preamble.

In this proposed rule, using LTCH cases from the December 2011 update of the FY 2011 MedPAR file, we identified 307 MS–LTC–DRGs that contained between 1 and 24 cases. This list of proposed MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing a minimum of 61 proposed MS–LTC–DRGs (307/5 = 61 with 2 proposed MS–LTC–DRG as the remainder). We assigned a proposed low-volume MS–LTC–DRG to a specific low-volume quintile by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Furthermore, because the number of MS–LTC–DRGs with less than 25 cases is not evenly divisible by 5, the average charge of the low-volume quintile was used to determine which of the proposed low-volume quintiles would contain the 2 additional proposed low-volume MS–LTC–DRGs. Specifically, after organizing the MS–LTC–DRGs by ascending order by average charge, we assigned the first fifth (1st through 55th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The proposed MS–LTC–DRGs with the highest average charge cases would be assigned into Quintile 5. Because the average charge of the 184th proposed low-volume MS–LTC–DRG in the sorted list is closer to the average charge of the 185th proposed low-volume MS–LTC–DRG (assigned to Quintile 4) than to the average charge of the 183rd proposed low-volume MS–LTC–DRG (assigned to Quintile 3), we are proposing to assign it to Quintile 4 (such that Quintile 4 contains 62 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below).

This process was repeated through the remaining proposed low-volume MS–LTC–DRGs so that 3 of the 5 low-volume quintiles contain 61 MS–LTC–DRGs (Quintiles 1, 2, and 3) and the other 2 low-volume quintiles contain 62 MS–LTC–DRGs (Quintiles 4 and 5). Table 13A, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the composition of the proposed low-volume quintiles for MS–LTC–DRGs for FY 2013.

Accordingly, in order to determine the proposed FY 2013 relative weights for the proposed MS–LTC–DRGs with low volume, we are proposing to use the 5 low-volume quintiles described above. The proposed composition of each of the 5 low-volume quintiles shown in Table 13A (listed in section VI. of the Addendum to this proposed rule and available via the Internet) was used in determining the proposed FY 2013 MS–LTC–DRG relative weights (as shown in Table 11 listed in section VI. of the Addendum to this proposed rule and available via the Internet). We determined a proposed relative weight and (geometric) average length of stay for each of the 5 low-volume quintiles using the methodology that we are proposing to apply to the proposed MS–LTC–DRGs (25 or more cases), as described in section VII.B.3.g. of this preamble. We are proposing to assign the same relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that made up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a proposed low volume of LTCH cases will vary in the future. We are proposing to use the most recent available claims data in the MedPAR file to identify proposed low-volume MS–LTC–DRGs and to calculate the proposed relative weights based on our methodology.

We note that we will continue to monitor the volume (that is, the number of LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the proposed MS–LTC–DRG relative weights result in appropriate payment for such cases and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2013 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to determine the FY 2013 MS–LTC–DRG relative weights based on our existing methodology. (For additional information on the original development of this methodology, and modifications to it since the adoption of the MS–LTC–DRGs, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55995) and the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43951 through 43966).) In summary, to determine the proposed FY 2013 MS–LTC–DRG relative weights, we are proposing to group LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintile (as described above). After grouping the cases to the appropriate MS–LTC–DRG (or low-volume quintile), we are proposing to calculate the proposed FY 2013 relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less (Steps 1 and 2 below). Next, we are proposing to adjust the number of cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (Step 3 below). After removing statistical outliers (Step 1 below) and cases with a length of stay of 7 days or less (Step 2 below), the SSO adjusted discharges and corresponding charges were then used to calculate proposed ''relative adjusted weights'' for each proposed MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method.

Below we discuss in detail the steps for calculating the proposed FY 2013 MS–LTC–DRG relative weights. We note that, as we discussed in section VII.B.3.c. of this preamble, we excluded the data of all-inclusive rate LTCHs, LTCHs that are paid in accordance with demonstration projects, and any Medicare Advantage claims in the December 2011 update of the FY 2011 MedPAR file.

Step 1—Remove statistical outliers.

The first step in the calculation of the proposed FY 2013 MS–LTC–DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the proposed MS–LTC–DRGs. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove cases with a length of stay of 7 days or less.

The proposed MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2013 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short stays. Therefore, consistent with our historical relative weight methodology, in determining the proposed FY 2013 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Adjust charges for the effects of SSOs.

After removing cases with a length of stay of 7 days or less, we are left with cases that have a length of stay of greater than or equal to 8 days. As the next step in the calculation of the proposed FY 2013 MS–LTC–DRG relative weights, consistent with our historical relative weight methodology, we are proposing to adjust each LTCH's charges per discharge for those remaining cases for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503).

We are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the proposed MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the proposed MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay

been equal to the average length of stay of the proposed MS–LTC–DRG.

Counting SSO cases as full discharges with no adjustment in determining the proposed FY 2013 MS–LTC–DRG relative weights would lower the proposed FY 2013 MS–LTC–DRG relative weight for affected proposed MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a proposed MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are proposing to adjust for SSO cases under § 412.529 in this manner because it results in more appropriate payments for all LTCH cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2013 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the FY 2013 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each LTCH case, we are proposing to calculate a hospital-specific relative charge value by dividing the SSO adjusted charge per discharge (see Step 3) of the LTCH case (after removing the statistical outliers (see Step 1) and LTCH cases with a length of stay of 7 days or less (see Step 2)) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce a proposed adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each proposed MS–LTC–DRG, we are proposing to calculate the proposed FY 2013 relative weight by dividing the average of the adjusted hospital-specific relative charge values (from above) for the proposed MS–LTC–DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated proposed MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its cases (that is, its case-mix) is calculated by dividing the sum of all the LTCH's proposed MS–LTC–DRG relative weights by its total number of cases. These LTCHs' hospital-specific relative charge values (from above) are then multiplied by these hospital-specific case-mix indexes. These hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process is continued until there is convergence between the weights produced at adjacent steps, for example, when the maximum difference is less than 0.0001.

Step 5—Determine a proposed FY 2013 relative weight for MS–LTC–DRGs with no LTCH cases.

As we stated above, we are proposing to determine the proposed FY 2013 relative weight for each proposed MS–LTC–DRG using total Medicare allowable total charges reported in the best available LTCH claims data (that is, the December 2011 update of the FY 2011 MedPAR file for this proposed rule). Using these data, we identified the proposed MS–LTC–DRGs for which there are no LTCH cases in the database, such that no patients who would have been classified to those proposed MS–LTC–DRGs were treated in LTCHs during FY 2011 and, therefore, no charge data are available for these proposed MS–LTC–DRGs. Thus, in the process of determining the proposed MS–LTC–DRG relative weights, we are unable to calculate proposed relative weights for the proposed MS–LTC–DRGs with no LTCH cases using the methodology described in Steps 1 through 4 above. However, because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are proposing to assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs and ''error'' MS–LTC–DRGs, as discussed below). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

In general, we are proposing to determine proposed FY 2013 relative weights for the proposed MS–LTC–DRGs with no LTCH cases in the December 2011 update of the FY 2011 MedPAR file used in this proposed rule (that is, proposed ''no-volume'' MS–LTC–DRGs) by cross-walking each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG with a calculated proposed relative weight (determined in accordance with the proposed methodology described above). Then, the proposed ''no-volume'' MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it is cross-walked (as described in greater detail below).

Of the 751 proposed MS–LTC–DRGs for FY 2013, we identified 213 proposed MS–LTC–DRGs for which there are no LTCH cases in the database (including the 8 ''transplant'' proposed MS–LTC–DRGs and 2 ''error'' proposed MS–LTC–DRGs). As stated above, we are proposing to assign relative weights for each of the 213 proposed no-volume MS–LTC–DRGs (with the exception of the 8 ''transplant'' proposed MS–LTC–DRGs and the 2 ''error'' proposed MS–LTC–DRGs, which are discussed below) based on clinical similarity and relative costliness to one of the remaining 538 (751 − 213 = 538) proposed MS–LTC–DRGs for which we are able to determine proposed relative weights based on FY 2011 LTCH claims data using the steps described above. (For the remainder of this discussion, we refer to the proposed ''cross-walked'' MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we crosswalk one of the 213 proposed ''no volume'' MS–LTC–DRGs for purposes of determining a proposed relative weight.) Then, we assigned the proposed no-volume MS–LTC–DRG the proposed relative weight of the proposed cross-walked MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

For this proposed rule, we are proposing to crosswalk the proposed no-volume MS–LTC–DRG to a proposed MS–LTC–DRG for which there are LTCH cases in the December 2011 update of the FY 2011 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. We evaluated the relative costliness in determining the applicable proposed MS–LTC–DRG to which a proposed no-volume MS–LTC–DRG is cross-walked in order to assign an appropriate proposed relative weight for the proposed no-volume MS–LTC–DRGs in FY 2013. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the proposed no-volume MS–LTC–DRGs in FY 2013, the proposed relative weights assigned based on the proposed cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on similar clinical similarity and

relative costliness, generally require equivalent relative resource use.

We are proposing to then assign the proposed relative weight of the proposed cross-walked MS–LTC–DRG as the proposed relative weight for the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2013. We note that if the proposed cross-walked MS–LTC–DRG had 25 cases or more, its proposed relative weight, which is calculated using the proposed methodology described in Steps 1 through 4 above, is assigned to the proposed no-volume MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume MS–LTC–DRG is cross-walked had 24 or less cases and, therefore, is designated to one of the low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable low-volume quintile to the proposed no-volume MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the proposed no-volume MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2013. (As we noted above, in the infrequent case where nonmonotonicity involving a proposed no-volume MS–LTC–DRG results, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

For this proposed rule, a list of the proposed no-volume MS–LTC–DRGs and the proposed MS–LTC–DRG to which it is cross-walked (that is, the proposed cross-walked MS–LTC–DRG) for FY 2013 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

To illustrate this methodology for determining the proposed relative weights for the FY 2013 MS–LTC–DRGs with no LTCH cases, we are providing the following example, which refers to the proposed no-volume MS–LTC–DRGs crosswalk information for FY 2013 provided in Table 13B.

Example: There are no cases in the FY 2011 MedPAR file used for this proposed rule for MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 70 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 61. Therefore, we assigned the same proposed relative weight of MS–LTC–DRG 70 of 0.8135 for FY 2013 to MS–LTC–DRG 61 (Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume of LTCH cases based on the system will vary in the future. We used the most recent available claims data in the MedPAR file to identify proposed no-volume MS–LTC–DRGs and to determine the proposed relative weights in this proposed rule.

Furthermore, for FY 2013, consistent with our historical relative weight methodology, we are proposing to establish proposed MS–LTC–DRG relative weights of 0.0000 for the following transplant proposed MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (proposed MS–LTC–DRG 1); Heart Transplant or Implant of Heart Assist System without MCC (proposed MS–LTC–DRG 2); Liver Transplant with MCC or Intestinal Transplant (proposed MS–LTC–DRG 5); Liver Transplant without MCC (proposed MS–LTC–DRG 6); Lung Transplant (proposed MS–LTC–DRG 7); Simultaneous Pancreas/Kidney Transplant (proposed MS–LTC–DRG 8); Pancreas Transplant (proposed MS–LTC–DRG 10); and Kidney Transplant (proposed MS–LTC–DRG 652). This is because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these proposed eight transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these proposed MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).)

Step 6—Adjust the proposed FY 2013 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

As discussed earlier in this section, the MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base DRG is subdivided into either two levels or the base DRG is not subdivided. The two-level subdivisions could consist of the DRG with CC/MCC and the DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the DRG with MCC and the DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and will result in higher average charges. Therefore, in the three severity levels, proposed relative weights should increase by severity, from lowest to highest. If the proposed relative weights decrease as severity increases (that is, if within a base proposed MS–LTC–DRG, a proposed MS–LTC–DRG with CC has a higher proposed relative weight than one with MCC, or the proposed MS–LTC–DRG ''without CC/MCC'' has a higher proposed relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Consequently, in determining the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule, consistent with our historical methodology, we are proposing to combine proposed MS–LTC–DRG severity levels within a base proposed MS–LTC–DRG for the purpose of computing a proposed relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity

that were made in determining the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

Step 7— Calculate the proposed FY 2013 budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). Under the budget neutrality requirement at § 412.517(b), for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the MS–LTC–DRG classifications and relative weights for FY 2013 based on the most recent available LTCH data, and to apply a budget neutrality adjustment in determining the proposed FY 2013 MS–LTC–DRG relative weights.

To ensure budget neutrality in the proposed update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. In this proposed rule, in the first step of our proposed MS–LTC–DRG budget neutrality methodology, for FY 2013, we are proposing to calculate and apply a proposed normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments are not influenced by changes in the composition of case types or the changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average CMI.

To calculate the proposed normalization factor for FY 2013 (the first step of our budget neutrality methodology), we are proposing to use the following three steps: (1.a.) we used the most recent available LTCH claims data (FY 2011) and grouped them using the proposed FY 2013 GROUPER (Version 30.0) and the proposed recalibrated FY 2013 MS–LTC–DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the Proposed FY 2013 MS–LTC–DRG Relative Weights above) to calculate the average CMI; (1.b.) we grouped the same LTCH claims data (FY 2011) using the FY 2012 GROUPER (Version 29.0) and FY 2012 MS–LTC–DRG relative weights and calculated the average CMI; and (1.c.) we computed the ratio of these average CMIs by dividing the average CMI for FY 2012 (determined in Step 1.b.) by the average proposed CMI for FY 2013 (determined in Step 1.a.). In determining the proposed MS–LTC–DRG relative weights for FY 2013, each proposed recalibrated MS–LTC–DRG relative weight was multiplied by 1.12393 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced proposed ''normalized relative weights.''

In the second step of our proposed MS–LTC–DRG budget neutrality methodology, we are proposing to determine a budget neutrality factor to ensure that estimated aggregate LTCH PPS payments (based on the most recent available LTCH claims data) after reclassification and recalibration (that is, the proposed FY 2013 MS–LTC–DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2012 MS–LTC–DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we are proposing to use FY 2011 discharge data to simulate payments and compare estimated aggregate LTCH PPS payments using the FY 2012 MS–LTC–DRGs and relative weights to estimate aggregate LTCH PPS payments using the proposed FY 2013 MS–LTC–DRGs and relative weights. Furthermore, consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to determine the budget neutrality adjustment factor for FY 2013 in the final rule.

For this proposed rule, we are proposing to determine the proposed FY 2013 budget neutrality adjustment factor using the following three steps: (2.a.) we simulated estimated total LTCH PPS payments using the proposed normalized relative weights for FY 2013 and proposed GROUPER Version 30.0 (as described above); (2.b.) we simulated estimated total LTCH PPS payments using the FY 2012 GROUPER (Version 29.0) and the FY 2012 MS–LTC–DRG relative weights in Table 11 of the Addendum to the FY 2012 IPPS/LTCH PPS final rule available on the Internet (76 FR 51813); and (2.c.) we calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2012 GROUPER (Version 29.0) and the FY 2012 MS–LTC–DRG relative weights (determined in Step 2.b.) by the estimated total LTCH PPS payments using the proposed FY 2013 GROUPER (Version 30.0) and the proposed normalized MS–LTC–DRG relative weights for FY 2013 (determined in Step 2.a.). In determining the proposed FY 2013 MS–LTC–DRG relative weights, each proposed normalized relative weight was multiplied by a budget neutrality factor of 0.9881603 (determined in Step 2.c.) in the second step of the proposed budget neutrality methodology to determine the proposed budget neutral FY 2013 relative weight for each proposed MS–LTC–DRG.

Accordingly, in determining the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.12393 and a budget neutrality factor of 0.9881603 (computed as described above). Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the proposed ''IPPS Comparable Thresholds'' (used in determining SSO payments under § 412.529(c)(3)), for FY 2013. The proposed FY 2013 MS–LTC–DRG relative weights in Table 11, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet, reflect both the proposed normalization factor of 1.12393 and the proposed budget neutrality factor of 0.9881603.

C. Proposed Use of a LTCH-Specific Market Basket Under the LTCH PPS

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the

''excluded hospital with capital'' market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket,'' as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a FY 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at § 413.40. Those types of hospitals are not paid under a PPS. Also, the FY 2002 cost structures for cancer and children's hospitals are noticeably different from the cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the FY 2002-based RPL market basket appears in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 21062), we expressed our interest in exploring the possibility of creating a stand-alone LTCH market basket that only reflects the cost structures for LTCHs. However, as we discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we were in the process of conducting further research to assist us in understanding the underlying reasons for the variations in costs and cost structures between freestanding IRFs and hospital-based IRFs, as well as between freestanding IPFs and hospital-based IPFs. At this time, we remain unable to sufficiently explain the observed differences in costs and cost structures between hospital-based IRFs and freestanding IRFs and between hospital-based IPFs and freestanding IPFs.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the FY 2002-based RPL market basket by creating and implementing an FY 2008-based RPL market basket. We also discussed that we were exploring the viability of creating two separate market baskets from the current RPL market basket: One market basket would include freestanding IRFs and freestanding IPFs and could be used to update payments under both the IPF and IRF payment systems. We continue our research in this area. The other market basket would be a stand-alone LTCH market basket. We stated that, depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle. We received several public comments in response to the FY 2012 proposed rule, all of which supported deriving a stand-alone LTCH market basket (76 FR 51756 through 51757).

As we routinely do, we have revisited the issue of the market basket used in the LTCH PPS. We previously did not estimate stand-alone market baskets for IRFs, IPFs, and LTCHs because of small sample sizes for freestanding facilities and the data concerns associated with the hospital-based facilities. Although we continue to do research in this area, at this time, we believe it is appropriate to move forward with a proposal to create a LTCH-specific market basket. This is because we believe we have sufficiently robust data to create such a market basket, and no longer need to rely on the cost report data from IPPS hospitals or from IRFs, IPFs, and LTCHs combined. Specifically, over the last several years, the number of LTCH facilities submitting a Medicare cost report has increased, helping to address concerns regarding the size of the available pool of facilities. The completeness and quality of the Medicare cost reports that we have been evaluating over the last several years have improved as well. Therefore, consistent with our intention to use the latest available and complete cost report data, we believe that it would be appropriate to create a market basket that would specifically reflect the cost structures of LTCHs based on Medicare cost report data for FY 2009, which are for cost reporting periods beginning on and after October 1, 2008, and before October 1, 2009. We are proposing to use data from cost reports beginning in FY 2009 because these data are the latest available complete data and, therefore, we believe it will enable us to accurately calculate cost weights that specifically reflect the cost structures of LTCHs. As a result, in this FY 2013 proposed rule, we are proposing to create a LTCH-specific market basket based solely on Medicare cost report data from LTCHs of which the majority of the reports are settled. In the following discussion, we provide an overview of the proposed market basket and describe the methodologies we are proposing to use for determining the operating and capital portions of the proposed FY 2009-based LTCH-specific market basket.

2. Overview of the Proposed FY 2009-Based LTCH-Specific Market Basket

The proposed FY 2009-based LTCH-specific market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use FY 2009 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price

change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

3. Proposed Development of a LTCH-Specific Market Basket

We are inviting public comments on our proposed methodology, discussed below, for deriving a LTCH-specific market basket.

a. Development of Cost Categories

(1) Medicare Cost Reports

The proposed FY 2009-based LTCH-specific market basket consists of several major cost categories derived from the FY 2009 LTCH Medicare cost reports as described previously, including wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance, capital, and a residual. These FY 2009 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2008, and before October 1, 2009. We are proposing to use FY 2009 as the base year because we believe that the FY 2009 Medicare cost reports represent the most recent, complete set of Medicare cost report data available for LTCHs.

Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer. Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we are proposing to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay that is within a comparable range of their total facility average length of stay. We believe this provides a more accurate reflection of the structure of costs for Medicare covered days. Similar to our methodology for the FY 2008-based RPL market basket, we are proposing to use the cost reports submitted by LTCHs with Medicare average lengths of stay within 15 percent (that is, 15 percent higher or lower) of the total facility average length of stay for the hospital. This is the same edit we applied to derive the FY 2008-based RPL market basket and generally includes those LTCHs with Medicare average length of stay within approximately 5 days of the facility average length of stay of the hospital.

Using this set of Medicare cost reports, we then calculated cost weights for six cost categories, and a residual category as represented by all other costs, directly from the FY 2009 Medicare cost reports submitted by LTCHs (found in Table VII.C–1 below). These Medicare cost report cost weights were then supplemented with information obtained from other data sources (explained in more detail below) to derive the proposed FY 2009-based LTCH-specific market basket cost weights.

The methodology used to develop the proposed FY 2009-based LTCH-specific market basket cost weights is generally the same methodology used to develop the FY 2008-based RPL market basket cost weights, with the exception of the employee benefits and contract labor cost weights. For the FY 2008-based RPL market basket, there was an issue with obtaining data specifically for employee benefits and contract labor from the set of FY 2008 Medicare cost reports, as IRFs, IPFs, and LTCHs were not required to complete the Medicare cost report worksheet from which these data were collected (Worksheet S3, Parts II and III). As a result, only a proportion of the total number of IRFs, IPFs, and LTCHs reported data for employee benefits and contract labor; therefore, we developed these cost weights for the FY 2008-based RPL market basket using data obtained from IPPS Medicare cost reports. However, when we reviewed LTCH Medicare cost reports for FY 2009, we found that a greater proportion of LTCHs submitted data for employee benefits and contract labor (approximately 40 percent of LTCHs, whose total costs account for approximately 50 percent of total costs for all LTCHs, submitted a cost report) compared to the proportion of IRFs and IPFs that submitted these data. We believe that it is better to use the LTCH-specific cost report data whenever possible to further our goal to create a market basket that represents the cost structures of LTCHs serving Medicare beneficiaries. Therefore, we are proposing to use the LTCH-specific cost reports to derive the employee benefits and contract labor cost weights for the proposed FY 2009-based LTCH-specific market basket, as opposed to using the IPPS Medicare cost reports as a proxy, as was done for the FY 2008-based RPL market basket.

TABLE VII.C–1—PROPOSED MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2009 MEDICARE COST REPORTS

Major cost categories	Proposed FY 2009-based LTCH-specific market basket cost weights obtained from Medicare cost reports (percent)
Wages and Salaries	40.407
Employee Benefits	6.984
Contract Labor	6.947
Professional Liability Insurance (Malpractice)	0.830
Pharmaceuticals	8.877
Capital	9.829
All Other (Residual)	26.126

(2) Other Data Sources

In addition to the data from Medicare cost reports submitted by LTCHs, the other data source we are proposing to use to develop the proposed FY 2009-based LTCH-specific market basket cost weights is the 2002 Benchmark Input-Output (I–O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. We are proposing to use the 2002 BEA Benchmark I–O data to disaggregate the ''All Other (Residual)'' cost category (26.126 percent) into more detailed hospital expenditure category shares. We note that we use these data to derive most of the CMS market baskets, including the FY 2008-based RPL and

FY 2006-based IPPS market baskets. The BEA Benchmark I–O accounts provide the most detailed information on the goods and services purchased by an industry, which allows for a more detailed disaggregation of expenses in the market basket for which we can then proxy the appropriate price inflation.

The BEA Benchmark I–O data are generally scheduled for publication every 5 years. The most recent data available are for 2002. BEA also produces Annual I–O estimates; however, the 2002 Benchmark I–O data represent a much more comprehensive and detailed set of data that are derived from the 2002 Economic Census. We used the 2002 BEA Benchmark I–O data for the FY 2008-based RPL market basket. Because BEA has not released new Benchmark I–O data, and we believe the data to be comprehensive and complete as indicated above, we are proposing to use the 2002 Benchmark I–O data in the proposed FY 2009-based LTCH-specific market basket.

Instead of using the less detailed Annual I–O data, we aged the 2002 Benchmark I–O data forward to 2009. The methodology we used to age the data forward involves applying the annual price changes from the respective price proxies to the appropriate cost categories. We repeat this practice for each year.

The ''All Other'' cost category expenditure shares are determined as being equal to each category's proportion to total ''All Other'' expenditures based on the aged 2002 Benchmark I–O data. For instance, if the cost for telephone services represented 10 percent of the sum of the ''All Other'' Benchmark I–O hospital expenditures, telephone services would represent 10 percent of the ''All Other'' cost category of the LTCH-specific market basket.

b. Cost Category Computation

As stated previously, for the proposed FY 2009-based LTCH-specific market basket, we are proposing to use data from the Medicare cost reports submitted by LTCHs to derive six major cost categories. The six major categories are: Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital, as shown above in Table VII.C–1. These represent the most detailed cost categories available from the Medicare cost reports, and, as stated above, in order to further disaggregate expenses, we then utilize the Benchmark I–O data. This is the same methodology used to derive most of the CMS market baskets, including the FY 2008-based RPL and FY 2006-based IPPS market baskets. The proposed FY 2009-based LTCH market basket includes the same major cost categories that were included in the FY 2008-based RPL market basket (76 FR 51758), and two additional categories, Employee Benefits and Contract Labor.

c. Selection of Price Proxies

After computing the FY 2009 cost weights for the proposed LTCH market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proxies for the operating portion of the proposed FY 2009-based LTCH market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

Producer Price Indexes—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because PPIs better reflect the actual price changes encountered by hospitals. For example, we are proposing to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we are proposing to use measure price changes at the final stage of production.

Consumer Price Indexes—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we are proposing to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is proposed to be used as a proxy for contracted food services.

Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table VII.C–2 below sets forth the proposed FY 2009-based LTCH-specific market basket, including the cost categories and their respective weights and price proxies. For comparison purposes, the corresponding FY 2008-based RPL market basket cost weights also are listed. For example, ''Wages and Salaries'' are 46.330 percent of total costs in the proposed FY 2009-based LTCH-specific market basket compared to 49.447 percent for the FY 2008-based RPL market basket. ''Employee Benefits'' are 8.008 percent in the proposed FY 2009-based LTCH-specific market basket compared to 12.831 percent for the FY 2008-based RPL market basket. As a result, compensation costs (wages and salaries plus employee benefits) for the proposed FY 2009-based LTCH market basket are 54.338 percent of total costs compared to 62.278 percent for the FY 2008-based RPL market basket. We note that the ''Wages and Salaries'' cost weight contained in Table VII.C–2 (46.330 percent) differs from that contained in Table VII.C–1 (40.407 percent). We attribute this difference to our allocation of the ''Contract Labor'' cost weight obtained from the Medicare cost reports (6.947 percent) proportionately across the ''Wages and Salaries'' and ''Employee Benefits'' cost weights obtained from the Medicare cost reports.

Following Table VII.C–2 is a summary of the proxies we are proposing to use for the operating portion of the proposed FY 2009-based LTCH-specific market basket. We note that the proxies we are proposing for the operating portion of the proposed FY 2009-based LTCH-specific market basket are the same as those used for the FY 2008-based RPL market basket. Because these proposed proxies meet our criteria of reliability, timeliness, availability, and relevance, we believe they are the best measures of price changes for the cost categories. For further discussion on the FY 2008-based RPL market basket, we refer readers to the discussion in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51759). The price proxies proposed for the capital portion of the proposed FY 2009-based LTCH market basket are the same as those used for the FY 2008-based RPL market basket (prior to any vintage weighting), as described in the

FY 2012 IPPS/LTCH PPS final rule (75 FR 51765), and as described in more detail in the capital methodology section in section VII.C.3.d. of the preamble of this proposed rule.

TABLE VII.C–2—PROPOSED FY 2009-BASED LTCH-SPECIFIC MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO FY 2008-BASED RPL MARKET BASKET COST WEIGHTS

Cost categories	Proposed FY 2009-based LTCH-specific market basket cost weights	FY 2008-based RPL market basket cost weights	Proposed FY 2009-based LTCH market basket price proxies
1. Compensation	54.338	62.278	
A. Wages and Salaries [1]	46.330	49.447	ECI for Wages and Salaries, Civilian Hospital Workers.
B. Employee Benefits [1]	8.008	12.831	ECI for Benefits, Civilian Hospital Workers.
2. Utilities	1.751	1.578	
A. Electricity	1.367	1.125	PPI for Commercial Electric Power.
B. Fuel, Oil, and Gasoline	0.281	0.371	PPI for Petroleum Refineries.
C. Water and Sewage	0.103	0.082	CPI–U for Water and Sewerage Maintenance.
3. Professional Liability Insurance	0.830	0.764	CMS Hospital Professional Liability Insurance Premium Index.
4. All Other Products and Services	33.252	26.988	
A. All Other Products	19.531	15.574	
(1.) Pharmaceuticals	8.877	6.514	PPI for Pharmaceutical Preparations for Human Use (Prescriptions).
(2.) Food: Direct Purchases	3.409	2.959	PPI for Processed Foods and Feeds.
(3.) Food: Contract Services	0.478	0.392	CPI–U for Food Away From Home.
(4.) Chemicals [2]	1.275	1.100	Blend of Chemical PPIs.
(5.) Medical Instruments	2.141	1.795	PPI for Medical, Surgical, and Personal Aid Devices.
(6.) Rubber and Plastics	1.329	1.131	PPI for Rubber and Plastic Products.
(7.) Paper and Printing Products	1.226	1.021	PPI for Converted Paper and Paperboard Products.
(8.) Apparel	0.250	0.210	PPI for Apparel.
(9.) Machinery and Equipment	0.127	0.106	PPI for Machinery and Equipment.
(10.) Miscellaneous Products	0.419	0.346	PPI for Finished Goods less Food and Energy.
B. All Other Services	13.721	11.414	
(1.) Labor-Related Services	5.349	4.681	
(a.) Professional Fees: Labor-Related	2.256	2.114	ECI for Compensation for Professional and Related Occupations.
(b.) Administrative and Business Support Services	0.508	0.422	ECI for Compensation for Office and Administrative Services.
(c.) All Other: Labor-Related Services	2.585	2.145	ECI for Compensation for Private Service Occupations.
(2.) Nonlabor-Related Services	8.372	6.733	
(a.) Professional Fees: Nonlabor-Related	5.332	4.211	ECI for Compensation for Professional and Related Occupations.
(b.) Financial Services	1.013	0.853	ECI for Compensation for Financial Activities.
(c.) Telephone Services	0.501	0.416	CPI–U for Telephone Services.
(d.) Postage	0.779	0.630	CPI–U for Postage.
(e.) All Other: Nonlabor-Related Services	0.747	0.623	CPI–U for All Items less Food and Energy.
5. Capital-Related Costs	9.829	8.392	
A. Depreciation	5.707	5.519	
(1.) Building and Fixed Equipment	3.838	3.286	BEA chained price index for Nonresidential Construction for Hospitals and Special Care Facilities—vintage weighted (20 years).
(2.) Movable Equipment	1.869	2.233	PPI for Machinery and Equipment—vintage weighted (8 years).
B. Interest Costs	2.434	1.954	
(1.) Government/Nonprofit	0.702	0.653	Average yield on Domestic Municipal Bonds (Bond Buyer 20 bonds)—vintage-weighted (20 years).
(2.) For Profit	1.732	1.301	Average yield on Moody's Aaa Bonds—vintage-weighted (20 years).
C. Other Capital-Related Costs	1.688	0.919	CPI–U for Residential Rent.
Total	100.000	100.000	

Note: Detail may not add to total due to rounding.

[1] Contract Labor is distributed to Wages and Salaries and Employee Benefits based on the share of total compensation that each category represents.

[2] To proxy the Chemicals cost category, we used a blended PPI composed of the PPI for Industrial Gas Manufacturing, the PPI for Other Basic Inorganic Chemical Manufacturing, the PPI for Other Basic Organic Chemical Manufacturing, and the PPI for Soap and Cleaning Compound Manufacturing. For more detail about this proxy, we refer readers to the FY 2012 IPPS/LTCH final rule (76 FR 51761).

(1) Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category.

(2) Employee Benefits

We are proposing to use the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category.

(3) Electricity

We are proposing to use the PPI for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category.

(4) Fuel, Oil, and Gasoline

We are proposing to use the PPI for Petroleum Refineries (BLS series code PCU324110324110) to measure the price growth of this cost category. We are proposing this proxy based on the same reasons set forth in the FY 2012 IPPS/LTCH final rule when this proxy was adopted for use in the FY 2008-based RPL market basket (76 FR 51761).

(5) Water and Sewage

We are proposing to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category.

(6) Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This method is also used to proxy PLI price changes in the Medicare Economic Index (75 FR 73268).

(7) Pharmaceuticals

We are proposing to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category.

(8) Food: Direct Purchases

We are proposing to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category.

(9) Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category.

(10) Chemicals

We are proposing to use a blended PPI composed of the PPI for Industrial Gas Manufacturing (NAICS 325120) (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (NAICS 325180) (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519), and the PPI for Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561). We are proposing to use this blended index based on the reasons as set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51761) when this proxy was adopted for use in the FY 2008-based RPL market basket.

(11) Medical Instruments

We are proposing to use the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category. We are proposing to use this index based on the reasons as set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51761 through 51762) when this proxy was adopted for use in the FY 2008-based RPL market basket.

(12) Rubber and Plastics

We are proposing to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category.

(13) Paper and Printing Products

We are proposing to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category.

(14) Apparel

We are proposing to use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category.

(15) Machinery and Equipment

We are proposing to use the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category.

(16) Miscellaneous Products

We are proposing to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category.

(17) Professional Fees: Labor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services.

(18) Administrative and Business Support Services

We are proposing to use the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category. We believe this compensation index appropriately reflects the changing price of labor associated with the provision of Administrative and Business Support Services.

(19) All Other: Labor-Related Services

We are proposing to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category.

(20) Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. This is the same price proxy that we are proposing to use for the Professional Fees: Labor-related cost category.

(21) Financial Services

We are proposing to use the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category. We believe that this compensation index appropriately reflects the changing price of labor associated with the provision of Financial Services.

(22) Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category.

(23) Postage

We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category.

(24) All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS

series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket.

d. Proposed Methodology for the Capital Portion of the Proposed FY 2009-Based LTCH-Specific Market Basket

In order to ensure consistency in the proposed FY 2009-based LTCH-specific market basket, we are proposing to calculate the capital-related cost weights using the same set of FY 2009 Medicare cost reports used to develop the operating cost weights with the same length-of-stay edit as applied when calculating the operating cost weights as described in section VII.C.3.a. of this preamble. The resulting proposed capital weight for the FY 2009 base year is 9.829 percent. We then separated the total capital cost weight into more detailed cost categories.

From the Medicare cost reports, we are able to derive cost weights for depreciation, interest, lease, and other capital-related expenses. Lease expenses are unique in that they are not broken out as a separate cost category in the proposed LTCH-specific market basket, but rather are proportionally distributed among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done in the FY 2008-based RPL market basket, we first assumed 10 percent of lease expenses represents overhead and assigned those costs to the Other Capital-Related Costs category accordingly. The remaining lease expenses were distributed across the three cost categories based on the respective weights of depreciation, interest, and other capital-related, not including lease expenses. This is the same method that was applied in the FY 2008-based RPL market basket.

Depreciation contains two subcategories: (1) Building and Fixed Equipment (or Fixed Assets); and (2) Movable Equipment. In the FY 2008-based RPL market basket, we disaggregated total depreciation expenses into Building and Fixed Equipment and Movable Equipment, using depreciation data from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs. Based on FY 2009 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 42 percent of total depreciation costs, while depreciation costs for movable equipment account for 58 percent of total depreciation costs. As mentioned above, we are proposing to allocate lease expenses among the ''Depreciation,'' ''Interest,'' and ''Other Capital'' cost categories. We determined that leasing building and fixed equipment expenses account for 80 percent of total leasing expenses, while leasing movable equipment expenses account for 20 percent of total leasing expenses. We are proposing to sum the depreciation and leasing expenses for building and fixed equipment together, as well as sum the depreciation and leasing expenses for movable equipment. This results in the final building and fixed equipment depreciation cost weight (after leasing costs are included) being 67 percent of total depreciation costs and the movable equipment depreciation cost weight (after leasing costs are included) being 33 percent of total depreciation costs. We note that total leasing costs account for approximately one-half of total capital expenses.

The total ''Interest'' cost category is split between government/nonprofit interest and for-profit interest. The FY 2008-based RPL market basket allocated 33 percent of the total ''Interest'' cost weight to government/nonprofit interest and proxied that category by the average yield on domestic municipal bonds. The remaining 67 percent of the ''Interest'' cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (76 FR 51760). This was based on the FY 2008 Medicare cost report data on interest expenses for government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs. For the proposed FY 2009-based LTCH-specific market basket, we are proposing to use the FY 2009 Medicare cost report data on interest expenses for government/nonprofit and for-profit LTCHs. Based on these data, we calculated a proposed 29/71 split between government/nonprofit and for-profit interest. We believe it is important that this split reflects the latest relative cost structure of interest expenses for LTCHs.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital portion of the proposed FY 2009-based LTCH-specific market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We are proposing to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the proposed FY 2009-based LTCH-specific market basket. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. The capital component of the proposed FY 2009-based LTCH market basket would reflect the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital purchases. However, the AHA does provide a consistent database of total expenses back to 1963. Consequently, we used data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then used data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2009.

In order to estimate capital purchases using data on depreciation expenses, the expected life for each cost category (Building and Fixed Equipment, Movable Equipment, and Interest) is needed to calculate vintage weights. For the FY 2008-based RPL market basket, we used FY 2008 Medicare cost reports for IPPS hospitals to determine the

expected life of building and fixed equipment and movable equipment (76 FR 51763). The FY 2008-based RPL market basket was based on an expected average life of building and fixed equipment of 26 years and an expected average life of movable equipment of 11 years, which were both calculated using data for IPPS hospitals. We believed that this data source reflected the latest relative cost structure of depreciation expenses for hospitals at the time and was analogous to freestanding IRFs, freestanding IPFs, and LTCHs.

The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Following a similar method to what was applied for the FY 2008-based RPL market basket, we are proposing to use the average expected life of building and fixed equipment to be equal to 20 years, and the average expected life of movable equipment to be 8 years. These expected lives are calculated using a 3-year average of data from Medicare cost reports for LTCHs for FY 2007 through FY 2009. We believe that using LTCH-specific data to calculate the expected lives of assets best reflects the cost structures of LTCH facilities.

We also are proposing to use the ''Building and Fixed Equipment'' and ''Movable Equipment'' cost weights derived from FY 2009 Medicare cost reports for LTCHs to separate the depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation. Year-end asset costs for building and fixed equipment and movable equipment were determined by multiplying the annual depreciation amounts by the expected life calculations. We then calculated a time series, back to 1963, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs. From this capital purchase time series, we were able to calculate the vintage weights for building and fixed equipment and for movable equipment. Each of these sets of vintage weights is explained in more detail below.

For the proposed building and fixed equipment vintage weights, we used the real annual capital purchase amounts for building and fixed equipment to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities. This is the same proxy used for the FY 2008-based RPL market basket. Because building and fixed equipment have an expected average life of 20 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 20-year periods. With real building and fixed equipment purchase estimates available from 2009 back to 1963, we averaged twenty-seven 20-year periods to determine the average vintage weights for building and fixed equipment that are representative of average building and fixed equipment purchase patterns over time. Vintage weights for each 20-year period are calculated by dividing the real building and fixed capital purchase amount in any given year by the total amount of purchases in the 20-year period. This calculation is done for each year in the 20-year period, and for each of the twenty-seven 20-year periods. We used the average of each year across the twenty-seven 20-year periods to determine the average building and fixed equipment vintage weights for the proposed FY 2009-based LTCH-specific market basket.

For the proposed movable equipment vintage weights, the real annual capital purchase amounts for movable equipment were used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amounts by the movable equipment price proxy, the PPI for Machinery and Equipment. This is the same proxy used for the FY 2008-based RPL market basket. Based on our determination that movable equipment has an expected average life of 8 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over an 8-year period. With real movable equipment purchase estimates available from 2009 back to 1963, thirty-nine 8-year periods were averaged to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. Vintage weights for each 8-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 8-year period. This calculation was done for each year in the 8-year period and for each of the thirty-nine 8-year periods. We used the average of each year across the thirty-nine 8-year periods to determine the average movable equipment vintage weights for the proposed FY 2009-based LTCH-specific market basket.

For the proposed interest vintage weights, the nominal annual capital purchase amounts for total equipment (building and fixed, and movable) were used to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). We are proposing that the vintage weights for interest should represent the average purchase pattern of total equipment over 20-year periods, which is the average useful life of building and fixed equipment as calculated using the LTCH Medicare cost report data. We believe vintage weights for interest should represent the average useful life of buildings and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. With nominal total equipment purchase estimates available from 2009 back to 1963, twenty-seven 20-year periods were averaged to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. Vintage weights for each 20-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 20-year period. This calculation is done for each year in the 20-year period and for each of the twenty-seven 20-year periods. We used the average of each year across the twenty-seven 20-year periods to determine the average interest vintage weights for the proposed FY 2009-based LTCH-specific market basket. The vintage weights for the capital portion of the FY 2008-based RPL market basket and the proposed FY 2009-based LTCH-specific market basket are presented in Table VII.C–4 below.

TABLE VII.C–4—FY 2008 RPL AND PROPOSED FY 2009 LTCH VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year	Building and fixed equipment		Movable equipment		Interest	
	FY 2008 26 years	FY 2009 20 years	FY 2008 11 years	FY 2009 8 years	FY 2008 26 years	FY 2009 20 years
1	0.021	0.034	0.071	0.102	0.010	0.021
2	0.023	0.037	0.075	0.108	0.012	0.024
3	0.025	0.039	0.080	0.114	0.014	0.026
4	0.027	0.042	0.083	0.123	0.016	0.029
5	0.028	0.043	0.085	0.129	0.018	0.032
6	0.030	0.045	0.089	0.134	0.020	0.035
7	0.031	0.046	0.092	0.142	0.021	0.037
8	0.033	0.047	0.098	0.149	0.024	0.040
9	0.035	0.049	0.103	.....	0.026	0.043
10	0.037	0.051	0.109	.....	0.029	0.047
11	0.039	0.053	0.116	.....	0.033	0.050
12	0.041	0.053	.....	.....	0.035	0.053
13	0.042	0.053	.....	.....	0.038	0.055
14	0.043	0.054	.....	.....	0.041	0.059
15	0.044	0.055	.....	.....	0.043	0.062
16	0.045	0.057	.....	.....	0.046	0.068
17	0.046	0.059	.....	.....	0.049	0.073
18	0.047	0.059	.....	.....	0.052	0.077
19	0.047	0.061	.....	.....	0.053	0.082
20	0.045	0.062	.....	.....	0.053	0.086
21	0.045	.....	.....	.....	0.055	.....
22	0.045	.....	.....	.....	0.056	.....
23	0.046	.....	.....	.....	0.060	.....
24	0.046	.....	.....	.....	0.063	.....
25	0.045	.....	.....	.....	0.064	.....
26	0.046	.....	.....	.....	0.068	.....
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. We are proposing to use the same price proxies (prior to any vintage weighting) for the capital portion of the proposed FY 2009-based LTCH market basket that were used in the FY 2008-based RPL market. We believe these are the most appropriate proxies for hospital capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

The price proxies (prior to any vintage weighting) for each of the capital cost categories, as shown in Table VII.C–2 above, are the same as those used for the FY 2008-based RPL market basket, as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51765), as well as the FY 2006-based Capital Input Price Index (CIPI) as described in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857). The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table VII.C–4 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at the following link: *http://www.cms.gov/Medicare ProgramRatesStats/05_Market BasketResearch.asp#TopOfPage* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule''.

e. Proposed FY 2013 Market Basket Update for LTCHs

For FY 2013 (that is, October 1, 2012, through September 30, 2013), we are proposing to use an estimate of the proposed FY 2009-based LTCH-specific market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimate the LTCH market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2012 forecast with history through the fourth quarter of 2011, the projected market basket update for FY 2013 is 3.0 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket update of 3.0 percent for FY 2013. Furthermore, because the proposed FY 2013 annual update is based on the most recent market basket estimate for the 12-month period (currently 3.0 percent), we also are proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2013 annual update in the final rule. (As discussed in greater detail in section V.A.2. of the Addendum to this proposed rule, we are proposing an annual update of 2.1 percent to the LTCH PPS standard Federal rate for FY 2013 under proposed § 412.523(c)(3)(viii) of the regulations.)

Using the current FY 2008-based RPL market basket and IGI's first quarter 2012 forecast for the market basket components, the FY 2013 market basket update would be 3.0 percent (before taking into account any statutory adjustment). Table VII.C–5 below compares the FY 2008-based RPL market basket and the proposed FY

2009-based LTCH-specific market basket percent changes.

TABLE VII.C–5—FY 2008-BASED RPL MARKET BASKET AND PROPOSED FY 2009-BASED LTCH MARKET BASKET PERCENT CHANGES; FY 2008 THROUGH FY 2015

Fiscal year (FY)	FY 2008-based RPL market basket index percent change	Proposed FY 2009-based LTCH market basket index percent change
Historical data:		
FY 2008	3.7	3.9
FY 2009	2.7	2.8
FY 2010	2.2	2.2
FY 2011	2.5	2.6
Average 2008–2011	2.8	2.9
Forecast:		
FY 2012	2.4	2.5
FY 2013	3.0	3.0
FY 2014	3.1	3.1
FY 2015	3.2	3.1
Average 2012–2015	2.9	2.9

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Insight, Inc. first quarter 2012 forecast.

For FY 2013, the proposed FY 2009-based LTCH-specific market basket update (as measured by percentage increase) is currently forecasted to be the same as the market basket update based on the FY 2008-based RPL market basket at 3.0 percent. The lower total compensation weight in the proposed FY 2009-based LTCH-specific market basket (54.338 percent) relative to the FY 2008-based RPL market basket (62.278 percent), absent other factors, would have resulted in a slightly lower market basket update for FY 2013 using the proposed FY 2009-based LTCH market basket. However, this impact is partially offset by the impact of the larger cost weights associated with the Pharmaceuticals and All Other Services cost categories. The net effect of these offsetting factors is that the market basket update is currently forecasted to be the same for FY 2013 based on the current FY 2008-based RPL market basket and the proposed FY 2009-based LTCH-specific market basket. As stated above, we are proposing that if more recent data (such as a revised IGI forecast) are subsequently available, we would use such data, if appropriate, to determine the FY 2013 annual update in the final rule.

f. Proposed FY 2013 Labor-Related Share

As discussed in section V.B. of the Addendum to this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. As discussed in more detail below and similar to the FY 2008-based RPL market basket and FY 2006 IPPS market basket (74 FR 43850), we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. Given this, based on our definition of the labor-related share, we are proposing to include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, All Other: Labor-related Services, and a portion of the Capital-Related cost weight. These are the same cost categories that were proposed and adopted in the FY 2012 labor-related share using the FY 2008-based RPL market basket, as we continue to believe these categories meet our criteria of being labor-intensive and whose costs vary with the local labor market. For a more detailed discussion of the selection of cost categories for inclusion in the FY 2012 labor-related share, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766). We note that, similar to the FY 2008-based RPL market basket and as described above, the wages and salaries and benefit cost weights reflect allocated contract labor costs.

For the FY 2008-based RPL market basket rebasing, in an effort to more accurately determine the share of professional fees for services such as accounting and auditing services, engineering services, legal services, and management and consulting services that should be included in the labor-related share, we obtained data from a survey of IPPS hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market. The results from this survey were then used to separate a portion of the Professional Fees cost category into labor-related and nonlabor-related costs. These results and our allocation methodology are discussed in more detail in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766). For the proposed FY 2009-based LTCH-specific market basket, we are proposing to apply these survey results using this same methodology to separate the Professional Fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We believe using the survey results serves as an appropriate proxy for the purchasing patterns of professional services for LTCHs as they also are providers of institutional care.

In addition to the professional services listed above, we also are proposing to classify expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories, as was done for the FY 2008-based RPL

market basket. The NAICS 55 industry is mostly comprised of corporate, subsidiary, and regional managing offices (otherwise referred to as home offices). As stated above, we classify a cost category as labor-related and include it in the labor-related share if the cost category is labor-intensive and if its costs vary with the local labor market. We believe many of the costs associated with NAICS 55 are labor-intensive and vary with the local labor market. However, data indicate that not all LTCHs with home offices have home offices located in their local labor market. Therefore, we are proposing to include in the labor-related share only a proportion of the NAICS 55 expenses based on the methodology described below.

For the FY 2008-based RPL market basket, we used data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices) and determined that 19 percent of the total number of freestanding IRFs, freestanding IPFs, and LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA). For a detailed discussion of this analysis, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51767).

For the proposed FY 2009-based LTCH-specific market basket, we conducted a similar analysis of home office data. However, instead of using data on freestanding IRF, freestanding IPF, and LTCHs, we began with the initial set of LTCH Medicare cost reports that were used to derive the cost weights for the proposed FY 2009-based LTCH-specific market basket. For consistency, we believe it is important for our analysis on home office data to be conducted on the same LTCHs used to derive the proposed FY 2009 LTCH market basket cost weights.

The Medicare cost report requires a hospital to report information regarding their home office provider. Approximately 82 percent of LTCHs reported some type of home office information on their Medicare cost report for FY 2009 (for example, home office number, city, state, zip code, or name). For the majority of these providers, we were able to identify in which MSA the LTCH's home office was located using the HOMER database and the Medicare cost reports. We then compared the home office MSA with the MSA in which the LTCH was located.

We found that 13 percent of the LTCHs with home offices had those home offices located in the same MSA as their facilities. We then concluded that these providers were located in the same local labor market as their home office. As a result, we are proposing to apportion the NAICS 55 expense data by this percentage. Thus, we are proposing to classify 13 percent of these costs into the ''Professional Fees: Labor-related Services'' cost category and the remaining 87 percent into the ''Professional Fees: Nonlabor-related Services'' cost category.

Using this proposed method and the IGI forecast for the first quarter 2012 of the proposed FY 2009-based LTCH-specific market basket, the proposed LTCH labor-related share for FY 2013 would be the sum of the FY 2013 relative importance of each labor-related cost category. Consistent with our proposal to update the labor-related share with the most recent available data, the labor-related share for this proposed rule reflects IGI's first quarter 2012 forecast of the proposed FY 2009-based LTCH-specific market basket. Table VII.C–6 below shows the proposed FY 2013 relative importance labor-related share using the proposed FY 2009-based LTCH-specific market basket and the FY 2012 relative importance labor-related share using the FY 2008-based RPL market basket.

TABLE VII.C–6—COMPARISON OF THE FY 2012 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2008-BASED RPL MARKET BASKET AND THE PROPOSED FY 2013 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE PROPOSED FY 2009-BASED LTCH MARKET BASKET

	FY 2012 relative importance labor-related share [1]	Proposed FY 2013 relative importance labor-related share [2]
Wages and Salaries	48.984	45.604
Employee Benefits	12.998	8.143
Professional Fees: Labor-Related	2.072	2.216
Administrative and Business Support Services	0.416	0.502
All Other: Labor-Related Services	2.094	2.513
Subtotal	66.564	58.978
Labor-Related Portion of Capital Costs (46%)	3.635	4.239
Total Labor-Related Share	70.199	63.217

[1] Published in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51767) and based on the second quarter 2011 IGI forecast.
[2] Based on the first quarter 2012 IGI forecast.

The proposed labor-related share for FY 2013 is the sum of the proposed FY 2013 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (FY 2009) and FY 2013. The sum of the proposed relative importance for FY 2013 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, and All Other: Labor-related Services) would be 58.978 percent, as shown in Table VII.C–6 above. We are proposing that the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the FY 2008-based RPL market basket. Because the relative importance for capital-related costs would be 9.216 percent of the proposed FY 2009-based LTCH-specific market basket in FY 2013, we are proposing to take 46 percent of 9.216 percent to determine the proposed labor-related share of capital-related costs for FY 2013 (.46 * 9.216). The result would be 4.239 percent, which we are proposing to add to 58.978 percent for the operating cost amount to determine the total proposed labor-related share for FY

2013. Thus, the labor-related share that we are proposing to use for the LTCH PPS in FY 2013 would be 63.217 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

D. Proposed Changes to the LTCH Payment Rates for FY 2013 and Other Proposed Changes to the LTCH PPS for FY 2013

1. Overview of Development of the LTCH Payment Rates

The basic methodology for determining LTCH PPS Federal prospective payment rates is set forth at § 412.515 through § 412.536. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal rate for FY 2013, that is, effective for LTCH discharges occurring on or after October 1, 2012 through September 30, 2013.

For further details on the development of the FY 2003 standard Federal rate when the LTCH PPS was initially implemented, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS Federal rate, we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); and FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773).

The proposed update to the LTCH PPS standard Federal rate for FY 2013 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual market basket update to the LTCH PPS standard Federal rate for FY 2013 are discussed below. Furthermore, as discussed in section VII.E.4. of this preamble, for FY 2013, in addition to the proposed update factor, we are proposing to make a one-time prospective adjustment to the standard Federal rate for FY 2013 so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years under existing § 412.523(d)(3) (this adjustment would not apply to payments made for discharges occurring on or before December 28, 2012, consistent with the statute). Furthermore, as discussed in section V.A. of the Addendum of this proposed rule, we are proposing to make an adjustment to the standard Federal rate to account for the estimated effect of the proposed changes to the area wage level adjustment for FY 2013 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4).

2. Proposed FY 2013 LTCH PPS Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. As discussed in section VII.C. of this preamble, we are proposing to adopt the newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to section VII.C.1. of this preamble.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the standard Federal rate and refers to the timeframes associated with such adjustments as a ''rate year.'' (The adjustments are discussed in more detail in section VII.D.2.b. of this preamble.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we employ ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the ''other adjustment'' specified in sections 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as ''the multifactor productivity (MFP) adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51770 through 51771), section 1886(b)(3)(B)(xi)(II) of the Act defines the MFP adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51691 through 51692 and 51771), we proposed and finalized that the end of the 10-year moving average of changes in the MFP should coincide with the end of the appropriate FY update period. Therefore, the MFP adjustment that is applied in determining any annual update to the LTCH PPS standard Federal rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act as they are both based on a fiscal year. As we established in that same final rule, the MFP adjustment is derived using a projection of MFP that is currently produced by IHS Global Insight, Inc. We established our methodology for calculating and applying the MFP adjustment in determining any annual update to the LTCH PPS standard Federal rate in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51772). In this proposed rule, we are not proposing to change our methodology

for calculating and applying the MFP adjustment to determine the annual update to the LTCH PPS standard Federal rate for FY 2013. (For details on the development of the MFP, including our finalized methodology for calculating and applying the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692).)

c. Proposed Market Basket Under the LTCH PPS for FY 2013

As discussed above in section VII.C. of this preamble, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to adopt a newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013 because we believe it appropriately reflects the cost structure of LTCHs. The proposed FY 2009-based LTCH-specific market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs.

d. Proposed Annual Market Basket Update for LTCHs for FY 2013

Consistent with our historical practice, we are proposing to estimate the proposed market basket update and the proposed MFP adjustment based on IGI's forecast using the most recent available data. As discussed in section VII.C.3.e. of this preamble, based on IGI's first quarter 2012 forecast, the proposed FY 2013 full market basket estimate for the LTCH PPS using the proposed FY 2009-based LTCH-specific market basket is 3.0 percent. Using our established methodology for determining the MFP adjustment (discussed in section VII.D.2.b. of this preamble), the current estimate of the proposed MFP adjustment for FY 2013 based on IGI's first quarter 2012 forecast is 0.8 percent. Consistent with our historical practice of using the best available data, we are proposing that if more recent data become available to determine the market basket estimate or the MFP adjustment, we would use such data for the final rule, if appropriate.

For FY 2013, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the standard Federal rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full FY 2013 market basket update by the FY 2013 MFP adjustment. To determine the market basket update for LTCHs for FY 2013, as reduced by the MFP adjustment, consistent with the approach we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771), we are proposing to subtract the FY 2013 MFP adjustment from the FY 2013 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act requires that any annual update to the standard Federal rate for FY 2013 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.1 percentage point for FY 2013. Therefore, following application of the productivity adjustment, we are proposing to reduce the adjusted market basket update (that is, the full market basket increase less the MFP adjustment) by the ''other adjustment'' specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act.

In this proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2013 full market basket estimate of 3.0 percent (based on the first quarter 2012 forecast of the proposed FY 2009-based LTCH-specific market basket) by the proposed FY 2013 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2013, as described in section VII.D.2.b. of the preamble of this proposed rule) of 0.8 percentage point (based on IGI's first quarter 2012 forecast). Following application of the proposed productivity adjustment, the proposed adjusted market basket update of 2.2 percent (3.0 percent minus 0.8 percentage point) is then reduced by 0.1 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act. Therefore, in this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish an annual market basket update under the LTCH PPS for FY 2013 of 2.1 percent (that is, the most recent estimate of the proposed LTCH PPS market basket update at this time of 3.0 percent less the proposed MFP adjustment of 0.8 percentage point less the 0.1 percentage point required under section 1886(m)(4)(C) of the Act). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (ix), which would specify that the standard Federal rate for FY 2013 is the standard Federal rate for the previous LTCH PPS year updated by 2.1 percent, and as further adjusted, as appropriate, as described in § 412.523(d). In addition, proposed § 412.523(c)(3)(ix)(B) would specify that, with respect to discharges occurring on or after October 1, 2012, and before December 29, 2012, payments are based on the standard Federal rate in proposed § 412.523(c)(3)(ix)(A) without regard to the one-time prospective adjustment provided for under proposed § 412.523(d)(3)(iii). As stated above, consistent with our historical practice of using the most recent available data, we are proposing that if more recent data become available when we develop the final rule, we would use such data, if appropriate, in determining the final market basket update under the LTCH PPS for FY 2013. (We note that we are proposing to adjust the FY 2013 standard Federal rate by a one-time prospective adjustment under proposed § 412.523(d)(3) (discussed in section VII.E.4. of this preamble) and a proposed area wage level budget neutrality factor in accordance with § 412.523(d)(4) (discussed in section V.B.5. of the Addendum of this proposed rule).)

3. Proposed LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), we established a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States (67 FR 56022). Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels.

Historically, we have used the most recent updated COLA factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp* to adjust the payments for LTCHs in Alaska and Hawaii. Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009) transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality. As we discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51809), we did not believe it was appropriate to use either the 2010 or 2011 reduced factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii for Medicare payment purposes.

Therefore, we established in that same final rule that, for FY 2012, we continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii.

We believe it was appropriate to use ''frozen'' COLA factors to adjust payments in FY 2012 while we explored alternatives for updating the COLA adjustment in the future because we believe those COLA factors appropriately adjusted the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska ad Hawaii, consistent with § 412.523(b) (76 FR 51809). In this proposed rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to use the same ''frozen'' COLA factors used in FY 2012 for FY 2013 and to update the COLA factors for Alaska and Hawaii, beginning in FY 2014, based on a comparison of the growth in the consumer price indices (CPIs) for Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). Specifically, in FY 2014, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we would update the COLA factors published by OPM that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay. Because the BLS publishes CPI data only for the cities of Anchorage and Honolulu, we are proposing to use a comparison of the relative growth in the overall CPI for those cities to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States are appropriate proxies for the relative price differences of the ''other areas'' of Alaska and Hawaii.

The BLS publishes the CPI for All Items for Anchorage, Honolulu, and for the average U.S. city. However, we are proposing to create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is comprised of approximately 60 percent commodities and 40 percent services. Therefore, we are proposing to create reweighted indexes for Anchorage, Honolulu, and the average U.S. city using the respective CPI commodities index and CPI services index using the approximate 60/40 share obtained from the IPPS market basket. We believe that proposing to use the underlying composition of the IPPS market basket nonlabor-related share to reweighted CPIs for each of the respective areas is an appropriate proxy for determining the COLA adjustments for LTCHs because both LTCHs and IPPS hospitals are required to meet the same certification criteria set forth in section 1861(e) of the Act to participate as a hospital in the Medicare program and generally experience similar nonlabor-related costs for providing inpatient hospital services. We also note that the composition of the proposed nonlabor-related share of the propose LTCH-specific market basket is not significantly different from the approximate 60/40 share obtained from the IPPS market basket.

We believe this proposed methodology is appropriate because we would be able to continue updating COLA adjustments for hospitals located in Alaska and Hawaii using the relative price differences as a proxy for relative cost differences. We believe this is an appropriate alternative methodology given the discontinuation of COLA factors from OPM. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent, and since the inception of the LTCH PPS, we have exercised our discretionary authority to adjust payments to LTCHs located in Alaska and Hawaii by incorporating this cap. Consistent with our existing policy, our proposed approach for FY 2014 would continue to use such a cap, as our proposal is based on OPM's COLA factors (updated by the proposed methodology described above). We note that this proposal is consistent with the proposal we are making for IPPS hospitals discussed in section II.B.2. of the Addendum to this proposed rule.

Lastly, we are proposing to update the COLA factors using this proposed methodology every 4 years (beginning in FY 2014), consistent with the proposal for updating the COLA factors under the IPPS discussed in section II.B.2. of the Addendum to this proposed rule. Under the IPPS, we are proposing to update the COLA factors every 4 years (beginning of FY 2014) concurrently with the update to the labor-related share of the IPPS market basket. The labor-related share of the IPPS market basket currently is not scheduled to be updated until FY 2014. At the time of development of the FY 2014 proposed rule, we expect to have CPI data available through 2012. Therefore, the proposed FY 2014 COLA factors for Alaska and Hawaii would be based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city.

In this proposed rule, for FY 2013, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, we are proposing to use the same COLA factors used to adjust payments in FY 2012 (which are based on OPM's 2009 COLA factors) by multiplying the nonlabor-related portion of the standard Federal payment rate by the proposed factors listed in the chart shown in section V.C. of the Addendum to this proposed rule. We believe that these proposed COLA factors would appropriately adjust the nonlabor-related portion of the standard Federal rate in FY 2013 for LTCHs located in Alaska and Hawaii, consistent with § 412.523(b).

E. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Facilities and the Increase in Number of Beds in LTCHs and LTCH Satellite Facilities

1. Background

Moratoria on the implementation of certain LTCH payment policies and on the development of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities established under sections 114(c) and (d) of the MMSEA (Pub. L. 110–173) as amended by section 4302 of the ARRA (Pub. L. 111–5) and further amended by sections 3106 and 10312 of the Affordable Care Act are set to expire during CY 2012, under current law.

The moratoria established by these provisions delayed the full implementation of the following policies for 5 years beginning at various times in CY 2007:

- The full application of the ''25-percent payment adjustment threshold'' to certain LTCHs, including hospitals-within-hospitals (HwHs) and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2012, or cost reporting periods beginning on or after October 1, 2007, and before October 1,

2012, as applicable under the regulations at §§ 412.534 and 412.536.

• The inclusion of an ''IPPS comparable'' option for payment determinations under the short stay outlier (SSO) adjustment at § 412.529 of the regulations for LTCH discharges occurring on or after December 29, 2007, but prior to December 29, 2012.

• The application of any one-time prospective adjustment to the LTCH PPS standard Federal rate provided for in § 412.523(d)(3) of the regulations from December 29, 2007, until December 29, 2012.

• In general, the development of new LTCHs and LTCH satellite facilities, or increases in the number of beds in existing LTCHs and LTCH satellite facilities from December 29, 2007, and ending December 28, 2012, unless one of the specified exceptions to the particular moratorium was met. (We refer readers to the May 22, 2008 interim final rule with comment period for the MMSEA (73 FR 29699, 29704 through 29707, 29709), the interim final rule for the ARRA (74 FR 43990 through 43992, and 43997), and the finalizing of the ACA changes in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399 through 50400, and 50416) for a complete description of this moratorium.)

In this proposed rule, we are proposing to extend the existing delay of the full implementation of the 25-percent payment adjustment threshold for an additional year; that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, as applicable. We also are proposing to make a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) of the regulations. We are proposing to phase in this proposed one-time prospective adjustment to the standard Federal rate over a 3-year period, beginning in FY 2013; however, consistent with the statute, this proposed adjustment would not apply to payments made for discharges occurring on or before December 28, 2012. We are not proposing to make any changes to the SSO policy as it currently exists in the regulations at § 412.529. Accordingly, consistent with the existing regulations at § 412.529(c)(3), for SSO discharges occurring on or after December 29, 2012, the ''IPPS comparable'' option at § 412.529(c)(3)(i)(D) would apply to payment determinations as appropriate for certain short stay cases. The moratoria on the development of new LTCHs or LTCH satellite facilities and on an increase in the number of beds in existing LTCHs or LTCH satellite facilities mandated by section 114(d) of the MMSEA, as amended by section 4302(b) of the ARRA and further amended by section 3106 and 10312 of the Affordable Care Act, are set to expire on December 29, 2012, under current law. As discussed later in this section, we are supportive of a statutory extension of these moratoria as we anticipate potential payment policy changes to the LTCH PPS as a result of CMS' research initiatives.

2. The 25-Percent Payment Adjustment Threshold

We are proposing to provide a 1-year extension (that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013) on the moratorium on the application of the 25-percent payment adjustment threshold policy as provided by section 144(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act. Therefore, we are proposing to revise §§ 412.534 and 412.536 of the regulations to reflect this proposed extension. Specifically, we are proposing to change ''2012'' to ''2013'' in §§ 412.534(c)(1)(i) and (ii), (c)(2)(1), (d)(1) and (2), and (e)(1) and (2) to incorporate this proposed change. In addition, we are proposing to revise the headings at §§ 412.534(c)(3), (d)(3), and (e)(3), and make conforming changes to (h)(4) and (5) and § 412.536(a)(2) to reflect this proposed 1-year extension. This proposed 1-year extension would continue the existing statutory exemption of grandfathered HwHs and freestanding LTCHs from the 25-percent payment adjustment threshold and the continued statutory increase in the percentage threshold to 50 or 75 percent, as applicable, for those LTCHs and LTCH satellite facilities presently so affected. For a detailed description of the moratorium on the ''25-percent threshold'' policy, we refer readers to the May 22, 2008 interim final rule with comment period (73 FR 29699 through 29704) and the interim final rule with comment period for the ARRA (74 FR 43990 through 43992).

Although we are proposing to extend the moratorium relating to the application of the 25-percent payment adjustment threshold policy for cost reporting period beginning on or after October 1, 2012, and before October 1, 2013, this moratorium will expire for certain classes of LTCHs prior to the effective date of the proposed extension. Specifically, under existing regulations, the moratoria on the ''25-percent threshold'' payment adjustment policies set forth in §§ 412.534(h) and 412.536 for a LTCH described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f) and a satellite facility of a LTCH described under § 412.22(h)(3)(i) (that is, a grandfathered HwH and a grandfathered LTCH satellite facility, respectively), and the moratoria on the ''25 percent threshold'' policies set forth in § 412.536 for a ''freestanding'' LTCH as described in § 412.23(e)(5) will expire beginning with discharges occurring in cost reporting periods beginning on or after July 1, 2012. In addition, under existing regulations, the moratorium on the ''25-percent threshold'' policies set forth in §§ 412.534(h) and 412.536 expire beginning with discharges occurring in cost reporting periods beginning on or after July 1, 2012, for a LTCH or a LTCH satellite facility that, as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location. Therefore, under our proposed policy, there will be a period during which the above-described LTCHs and LTCH satellite facilities must comply with §§ 412.534 and 412.536 before becoming subject to the moratoria again. The period during which the above-described LTCHs and LTCH satellite facilities would comply with §§ 412.534 and 412.536 would be for discharges occurring in cost reporting periods beginning on or after July 1, 2012, and before July 1, 2013. Then, for discharges occurring in cost reporting periods beginning on or after July 1, 2013, and before July 1, 2014, the above-described LTCHs and LTCH satellite facilities would be under the proposed extension of the moratorium. We note that, if our proposal is finalized, the proposed policy would be effective prospectively, consistent with the prospective nature of the FY 2013 rulemaking.

We are proposing a 1-year extension in the delay of the full application of the 25-percent payment adjustment threshold policy because we believe, based on recent research as explained in greater detail below, that we could be in a position within the near future to propose revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary. In light of this potential result, we believe it is prudent to avoid requiring LTCHs (or CMS payment processing systems) to retool in order to implement the full reinstatement of the policy for what could be a relatively short period of time.

We originally instituted the 25-percent payment adjustment threshold policy for co-located LTCHs and LTCH satellite facilities in the FY 2005 IPPS

final rule (69 FR 49191 through 49214), and expanded it to all ''subclause I'' LTCHs in RY 2008 (72 FR 26919 through 26944) because our data and medical reviews revealed a strong pattern of correlations between growing numbers of patient discharges from IPPS hospitals to onsite or neighboring LTCHs after shorter lengths of stay at the IPPS hospitals and significant and increasing costs to the Medicare program. Our concern was that such patient shifting by providers could be financially, rather than clinically, motivated and that many LTCHs, in effect, were functioning as long-stay units of IPPS hospitals, a configuration not permitted under the governing statute. Section 1886(d)(1)(B) of the Act provides for an exclusion of LTCHs from the IPPS for acute care hospitals. While the statute provides for an exclusion for psychiatric units and rehabilitation units, it does not provide for an exclusion for long-term care units. Our goal was to ''challenge'' this otherwise unrestricted flow of patients from one provider to the other which we believed was resulting in two Medicare payments, one to the IPPS hospital and one to the LTCH, for what often could be understood as one episode of care. The policy was aimed at altering both the financial benefits accruing to the providers and the resulting increasing costs to the Medicare program by establishing a percentage threshold for patient shifting beyond which a payment adjustment would be applied to the LTCH discharge. The policy did not include patients who had been a high-cost outlier case at the IPPS hospital prior to discharge to the LTCH in the calculation of the percentage threshold. The attainment of high-cost outlier status serves as a ''benchmark,'' which we believe indicates that there has not been a premature discharge from the IPPS hospital.

In addition, in several reports to the Congress (June 2003, Chapter 5; June 2004, Chapter 5; and March 2011, Chapter 10), MedPAC recommended the development of patient-level and facility-level criteria for LTCHs. It was MedPAC's belief that developing facility-level criteria would standardize the level and delivery of services provided by all LTCHs and that applying patient-level criteria would limit the type of beneficiaries admitted. The criteria would target the particular subgroup of beneficiaries who could derive the most clinical benefit from the long-stay and specialized hospital-level treatment at LTCHs while justifying the high Medicare payments in light of concerns about cost effectiveness and the program's commitment to value-based purchasing decisions (MedPAC's Report to Congress, June 2004, p. 128 through 131).

MedPAC's March 2011 Report to Congress (page 238) included the following statement:

> Previous research by the Commission found that the type of patients long-term care hospitals (LTCHs) treat are often cared for in alternative settings, such as acute care hospitals and skilled nursing facilities (SNFs) (Medicare Payment Advisory Commission 2004). The Commission found that Medicare pays more for patients using LTCHs than for similar patients using other settings; however the payment difference narrowed considerably if LTCH care was targeted to the most severely ill patients. The Commission has therefore argued that, while LTCHs appear to have value for very sick patients, they are too expensive to be used for patients who could be treated in less intensive settings.

Since MedPAC's 2004 recommendations for the development of patient-level and facility-level criteria for LTCHs, CMS has awarded research contracts for the purposes of exploring the feasibility of such criteria as a basis for ''ensuring that appropriate patients are treated in long-term care hospitals'' (MedPAC's March 2011 Report to Congress, p. 238). Specifically, in response to MedPAC's 2004 recommendation for the development of patient-level and facility-level criteria, CMS awarded research contracts to Research Triangle International, Inc. (RTI). Summaries of work done by RTI have been published in rules issued in the **Federal Register** for FY 2007 (71 FR 27884 through 27885), for FY 2008 (72 FR 4884 through 4886), and FY 2009 (73 FR 5374 through 5377). Reports on the research are posted on the Web site at: *http://www.cms.gov/LongTermCareHospitalPPS/02a_RTIReports.asp#TopOfPage.* As these researchers discovered, developing LTCH-specific patient-level criteria has been extremely difficult. This is because patients fitting the profile of LTCH patients (clinically complex, with multiple acute and chronic conditions) are far more likely to be treated in IPPS hospitals nationwide than they are in LTCHs, with over 3,500 general acute care hospitals as compared to approximately 440 LTCHs and with the number of LTCHs highly concentrated in some areas and nonexistent in others.

More recently, during the last 2 years, CMS has been engaged with contractors in two projects that appear to be moving toward addressing the concerns and perhaps realizing the goals that MedPAC articulated in its recommendations, quoted above. We believe that, within the near future, we could potentially be in a position to recommend revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary. We are also aware that the LTCH industry has requested legislators to, among other things, forestall the reinstatement of the full implementation of the 25-percent payment adjustment threshold policy at this time. In acknowledgement of hopeful research outcomes as well as concerns raised by the industry, we are proposing a 1-year extension (that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013) of the existing moratoria on the full application of the 25-percent payment adjustment threshold policy as provided by section 144(c) of the MMSEA as amended by section 4302(a) of the ARRA and section 3106(c) and 10312(a) of the Affordable Care Act.

3. The ''IPPS Comparable Per Diem Amount'' Payment Option for Very Short Stays Under the Short-Stay Outlier (SSO) Policy

Prior to the enactment of section 114(c)(3) of the MMSEA, for LTCH short stay outlier (SSO) cases with a covered length of stay that was equal to or less than one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS (that is, the ''IPPS comparable threshold''), the SSO payment adjustment determination included an additional option, the ''IPPS comparable amount per diem amount'' (72 FR 26906). This policy was implemented in our regulations at § 412.529(c)(3)(i) in the RY 2008 LTCH PPS final rule (72 FR 26904 through 26908).

Section 114(c)(3) of the MMSEA as amended by section 3106(a) of the Affordable Care Act provided a 5-year moratorium from the application of the ''IPPS comparable amount'' option under the SSO payment adjustment, which is scheduled to expire for discharges beginning on or after December 29, 2012 (75 FR 50399 through 50400). With the expiration of the moratorium, payment for an SSO discharge occurring on or after December 29, 2012, the Medicare payment will be based on the least of the following:

- 100 percent of the estimated cost of the case.
- 120 percent of the MS–LTC–DRG specific per diem amount multiplied by the covered length of stay of the particular case.
- The full MS–LTC–DRG per diem amount.

• Comparing the covered length of stay for as an SSO case and the ''IPPS comparable threshold,'' one of the following:

1. The blend of the 120 percent of the MS–LTC–DRG specific per diem amount (specified in § 412.529(d)(1)) and an amount comparable to the IPPS per diem amount (specified in § 412.529(d)(4)), for cases where the covered length of stay for an SSO case is greater than the ''IPPS comparable threshold'' (as specified under § 412.529(c)(3)(ii)).

2. An amount comparable to the IPPS comparable per diem amount (specified in § 412.529(d)(4)), if the covered length of stay for an SSO case is equal to or less than one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS (the ''IPPS comparable threshold''), as specified under § 412.529(d)(4).

For a comprehensive discussion of the SSO policy, including the payment for very short stays under the SSO policy, we refer readers to the May 6, 2008 interim final rule with comment period (73 FR 24874 through 24881).

The proposed FY 2013 ''IPPS comparable thresholds'' (that is, one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS used in determining SSO payments for discharges occurring on or after December 29, 2012, under § 412.529(c)(3) of the regulations are provided in Table 11, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

Technical change. With the expiration of the moratorium on the application of the ''IPPS comparable per diem amount'' option at § 412.529(c)(3)(i)(D) to the determination of the payment adjustment under the SSO policy, described above, we are proposing to make a technical change to the regulation text at § 412.529(d)(4)(i)(C) in order to clarify the application of our policy. Specifically, at § 412.529(d)(4)(i)(C), we are proposing to remove the following introductory phrase that appears at the beginning of the paragraph: ''For purposes of the blend amount described in paragraph (c)(2)(iv) of this section,'' so that the provision of the paragraph is not limited only to the ''blend amount'' option under the SSO policy at § 412.529(c)(2)(iv), but is also applicable to the ''IPPS comparable per diem amount'' option at § 412.529(c)(3)(i)(D). We are proposing to clarify this policy by revising the language of paragraph (d)(4)(i)(C) to read as follows:

''(C) The payment amount specified under paragraph (d)(4)(i)(B) of this section may not exceed the full amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system determined under paragraph (d)(4)(i)(A) of this section.''

We are proposing this technical correction in order to clarify that, payment for a case based solely on the ''IPPS comparable per diem amount'' described at § 412.529(d)(4) is calculated in the same way that it is calculated when payment for a case will be based on the ''blend amount'' (under § 412.529(c)(2)(iv)) of the ''IPPS comparable per diem amount'' and the ''120 percent of the LTC–DRG specific per diem payment amount.'' When we finalized the ''IPPS comparable per diem amount'' option to the SSO payment adjustment in the RY 2008 LTCH PPS final rule we stated in the preamble that ''the IPPS comparable per diem amount [was] capped at the full IPPS comparable amount that is used under the blend option of the current SSO policy * * *'' (72 FR 26907). However, we neglected, at that time, to revise the regulation text. Therefore, we are proposing to clarify our regulations at § 412.52(d)(4)(i)(C) to reflect existing policy that the ''IPPS comparable per diem amount'' is calculated as a per diem that is capped at an amount comparable to what would have been a full payment under the inpatient prospective payment system, such that an SSO payment made under the ''IPPS comparable per diem amount'' option may also not exceed the full amount comparable to what would otherwise be paid under the inpatient prospective payment system.

4. Proposed One-Time Prospective Adjustment to the Standard Federal Rate Under § 412.523(d)(3)

In the August 30, 2002 LTCH PPS final rule (67 FR 55954), we set forth regulations implementing the LTCH PPS, based upon the broad authority granted to the Secretary, under section 123 of the BBRA (as amended by section 307(b) of the BIPA). Section 123(a)(1) of the BBRA required that the system ''maintain budget neutrality.'' The statute requires the LTCH PPS to be budget neutral in FY 2003, so that estimated aggregate payments under the LTCH PPS for FY 2003 would be equal to the estimated aggregate payments that would have been made if the LTCH PPS were not implemented for FY 2003. The methodology for determining the LTCH PPS standard Federal rate for FY 2003 that would ''maintain budget neutrality'' is described in considerable detail in the August 30, 2002 final rule (67 FR 56027 through 56037). Our methodology for estimating payments for the purposes of budget neutrality calculations used the best available data, and necessarily reflected several assumptions (for example, costs, inflation factors and intensity of services provided) in estimating aggregate payments that would be made if the LTCH PPS was not implemented. In performing our budget neutrality calculations, we took into account the statute's requirement that certain statutory provisions that affect the level of payments to LTCHs in years prior to the implementation of the LTCH PPS shall not be taken into account in the development and implementation of the LTCH PPS. Specifically, section 307(a)(2) of the BIPA requires that the increases to the target amounts and the increases to the cap on the target amounts for LTCHs provided for by section 307(a)(1) of the BIPA (as set forth in section 1886(b)(3)(J) of the Act) and the enhanced continuous improvement bonus (CIB) payments for LTCHs provided for by section 122 of the BBRA (as set forth in section 1886(b)(2)(E) of the Act) are not to be taken into account in the development and implementation of the LTCH PPS.

In the August 30, 2002 final rule, we also stated our intentions to monitor LTCH PPS payment data to evaluate whether later data varied significantly from the data available at the time of the original budget neutrality calculations (for example, data related to inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). To the extent the later data significantly differ from the data employed in the original calculations, the aggregate amount of payments during FY 2003 based on later data may be higher or lower than the estimates upon which the budget neutrality calculations were based. Therefore, in that same final rule, under the broad authority conferred upon the Secretary in developing the LTCH PPS, including the authority for establishing appropriate adjustments, provided by section 123(a)(1) of the BBRA, as amended by section 307(b) of BIPA, we provided in § 412.523(d)(3) of the regulations for the possibility of making a one-time prospective adjustment to the LTCH PPS rates by a deadline of October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS would not be perpetuated in the LTCH PPS rates for future years. This deadline was revised to July 1, 2008, in the RY 2007 LTCH PPS final rule

because sufficient time had not elapsed since the start of the LTCH PPS for new data to be generated that would have enabled us to conduct a comprehensive reevaluation of our budget neutrality calculations (71 FR 27842 through 27844). Therefore, we did not implement the one-time prospective adjustment provided under § 412.523(d)(3) at that time; however, we stated that we would continue to collect and interpret new data as it became available in order to determine whether we should propose such an adjustment in the future. Furthermore, we revised § 412.523(d)(3) by changing the original October 1, 2006 deadline to July 1, 2008, to postpone the prospective one-time adjustment due to the time lag in the availability of Medicare data upon which a proposed adjustment would be based, noting that there is a lag time between the submission of claims data and cost report data, and the availability of that data in the MedPAR files and HCRIS, respectively. We also explained that we believed that postponing the deadline of the prospective one-time prospective adjustment to the LTCH PPS rates provided for in § 412.523(d)(3) to July 1, 2008, would allow our decisions regarding a possible adjustment to be based on more complete and up-to-date data (71 FR 27842 through 27845).

Section 114(c)(4) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173) (MMSEA) provides that the ''Secretary shall not, for the 3-year period beginning on the date of the enactment of this Act, make the one-time prospective adjustment to long-term care hospital prospective payment rates provided for in section 412.523(d)(3) of title 42, Code of Federal Regulations, or any similar provision.'' That provision delayed the effective date of any one-time prospective adjustment until no earlier than December 29, 2010. Accordingly, we revised § 412.523(d)(3) of the regulations to conform with this requirement (73 FR 26801 through 26804 and 26839). Then, section 3106 of the Affordable Care Act amended section 114(c) of the MMSEA by specifying an additional 2-year delay in the one-time prospective adjustment to the standard Federal rate at § 412.523(d)(3). Thus, under current law the Secretary is precluded from making the one-time adjustment to standard Federal rate until December 29, 2012. Therefore, we revised § 412.523(d)(3) to conform with this requirement (75 FR 50399 and 50416).

Prior to the statutory delay in the application of any one-time prospective adjustment required when the MMSEA was enacted on December 29, 2007, we had developed a methodology for evaluating whether to propose a one-time prospective adjustment under § 412.523(d)(3) of the regulations. In order to inform the public of our thinking, and to stimulate comments for our consideration during the statutory delay in implementing any one-time prospective adjustment, we discussed our analysis and its results in the RY 2009 LTCH PPS proposed and final rules (73 FR 5353 through 5360 and 26800 through 26804, respectively).

Evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) requires a thorough review of the relevant LTCH data (as described below). As we discussed in the RY 2009 LTCH PPS proposed and final rules, we conducted a thorough review of the relevant data, that is, cost data from FY 2002, representing the final year LTCHs were paid under the TEFRA payment system. The cost report data for FY 2002 is comprised of a high proportion of settled and audited cost reports submitted by LTCHs. We also have payment data on the first year of the LTCH PPS (that is, FY 2003). On the basis of our review of these data sources, we discussed a potential methodology for determining whether the one-time prospective adjustment provided for under § 412.523(d)(3) of the regulations should be proposed and the computation an adjustment, if appropriate, based on that potential methodology. We also discussed that under that potential methodology, our analysis indicated that a permanent adjustment factor of 0.9625 to the LTCH PPS standard Federal rate could be warranted. Consistent with the requirements of section 114(c)(4) of the MMSEA, which delayed the implementation of such an adjustment, we did not propose any one-time prospective adjustment to the standard Federal rate. However, we presented our analysis and welcomed public comment to inform the public of our analysis if and when we decide to propose (and ultimately finalize) such an adjustment under § 412.523(d)(3).

As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26803), our policy objective in providing for this one-time prospective adjustment has always been to ensure that computations based on the earlier, necessarily limited (but at that time best available) data available at the inception of the LTCH PPS would not be built permanently into the rates if data available at a later date could provide more accurate results. When we established the FY 2003 standard Federal rate in a budget neutral manner, we used the most recent LTCH cost data available at that time (that is, FY 1999 data), and trended that data forward to estimate what Medicare would have paid to LTCHs in FY 2003 under the TEFRA payment system if the PPS were not implemented for FY 2003. As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26803), after a thorough evaluation of the currently available data in light of this stated policy objective, we believe that the most appropriate methodology for evaluating an adjustment to the original budget neutrality adjustment would be to compare estimated payments in the first year under the LTCH PPS to what estimated payments would have been under the prior TEFRA payment system for that year based on the best available data. Accordingly, in that same final rule, we revised § 412.523(d)(3) to provide for the possibility of making a one-time prospective adjustment to LTCH PPS rates so that ''the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.''

The regulations at § 412.523(d)(3) provide that the Secretary may make a one-time prospective adjustment to the LTCH PPS rates in order to ensure that any ''significant'' difference is not perpetuated in the LTCH PPS rates for future years. The regulation does not specifically define what constitutes a significant difference for this purpose. In this proposed rule, in evaluating whether a one-time prospective adjustment under § 412.523(d)(3) is warranted, we are proposing to consider as ''significant'' any difference greater than or equal to a 0.25 percentage point difference between the original budget neutrality calculations and budget neutrality calculations based on the more recent data now available. As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26804), we believe this proposed threshold would avoid making an adjustment to account for very minor deviations between earlier and later estimates of budget neutrality. It would also be consistent with thresholds that we employ for similar purposes in other prospective payment systems. For example, under the capital IPPS, we make a forecast error correction in the framework used to update the capital Federal rate if a previous forecast of input prices varies by at least a 0.25 percentage point from actual input price changes (72 FR 47425). We do not

believe that we should treat differences greater than or equal to 0.25 percent as not ''significant,'' since the effect of any difference would be magnified as the rates are updated each year.

In order to determine whether a one-time prospective adjustment would be warranted, as we discussed in the RY 2009 LTCH PPS proposed and final rules, we evaluated several issues regarding the data to use for this purpose. These issues and our proposals related to these issues are discussed below.

As noted previously, as we considered the appropriateness of a one-time prospective adjustment to the standard Federal rate, it is necessary to estimate both aggregate payments under the LTCH PPS for FY 2003 and the estimated aggregate payments that would have been made under the TEFRA system in FY 2003 if the LTCH PPS were not implemented. While it is possible to determine actual TEFRA payments to LTCHs for FY 2002, the last year of payment under that methodology, it is necessary to estimate what TEFRA payments would have been in FY 2003 if the new LTCH PPS had not been implemented. In developing our proposed methodology for evaluating a one-time prospective adjustment, we considered whether we should use actual FY 2003 costs to calculate estimated TEFRA payments for FY 2003 or use costs for FY 2002 trended forward to FY 2003 as the basis for the calculation. As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26802), basing the estimate on actual FY 2003 costs would have the considerable advantage of avoiding the need to inflate FY 2002 costs to FY 2003 costs. However, there is also a potentially serious disadvantage to using actual FY 2003 costs. Because FY 2003 was the first year of payment under the LTCH PPS, the cost experience of LTCHs in that year would reflect their response to the incentives provided by the new payment system, instead of reflecting behavior under the reasonable cost payment system. Indeed, implementation of an LTCH PPS should directly affect the behavior of LTCHs, and, therefore, the level of costs in LTCHs. One of the incentives of a PPS is to improve efficiency in the delivery of care, which generally results in decreased cost per discharge. For this reason, using FY 2003 costs directly could be a poor basis for estimating payments that ''would have been made if the LTCH PPS were not implemented.'' On balance, however, we believe that trending forward for 1 year the costs incurred under the last year of the TEFRA payment system poses a smaller prospect for distortion than using costs incurred during the subsequent year, when the incentives faced by LTCHs to reduce costs could have had a significant effect. We also note that some LTCH stakeholders have expressed concern that using FY 2003 costs directly would provide a poor basis upon which to estimate payments that ''would have been made if the LTCH PPS were not implemented'' for precisely the reasons discussed above. Therefore, we believe that basing the estimate of FY 2003 TEFRA payments on FY 2002 costs trended forward should satisfy these concerns.

In this proposed rule, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we are proposing to base our calculation of the estimated aggregate payments that would have been made if the LTCH PPS were not implemented (that is, estimated FY 2003 TEFRA payments) on FY 2002 costs trended forward for the reasons discussed above. Specifically, under our proposed methodology, we trended forward the most recent available LTCH FY 2002 costs to FY 2003 using the excluded hospital market basket, because we believe these data best reflect the price changes in hospital inpatient costs realized by LTCHs from FY 2002 to FY 2003. We believe using the excluded hospital market basket to update FY 2002 reasonable cost-based (TEFRA) payments in order to estimate FY 2003 TEFRA payments is appropriate because the TEFRA payment system under which LTCHs were paid prior to the implementation of the LTCH PPS utilized the excluded hospital market basket to update the hospital-specific limits on payment for operating costs of LTCHs. In addition, we used the excluded hospital market basket to update the inpatient hospital operating and capital costs of LTCHs when we developed the initial LTCH PPS standard Federal rate for FY 2003 (67 FR 56029 through 56031). We believe that the LTCH cost report data for FY 2002 currently available is appropriate to use for this purpose because, as noted above, it is comprised of settled and audited cost reports submitted by LTCHs. (We note that this is the same methodology for evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed and final rules (73 FR 5356 and 26802, respectively).)

As discussed above, to determine whether a one-time prospective adjustment under § 412.523(d)(3) may be warranted, we believe that an estimate of the payments that would have been made in FY 2003 under the TEFRA methodology should be compared to estimated payments under the new LTCH PPS in FY 2003. We explained in the RY 2009 LTCH PPS final rule (73 FR 26802) that the most direct way to determine payments under the new LTCH PPS is simply to aggregate the actual payments calculated under the LTCH PPS methodology for the discharges that occurred during the first year of the LTCH PPS (FY 2003). However, that approach raises an issue of consistency since the discharges for which Medicare payments were made under the LTCH PPS during FY 2003 are not the same as the discharges for which costs were incurred during the last year of payment under the TEFRA methodology, FY 2002. For these reasons discussed above, we believe that the best way to estimate the TEFRA payments that would have been made to LTCHs during FY 2003 is to use inflated FY 2002 costs as a proxy for FY 2003 costs. Comparing actual FY 2003 LTCH PPS payments to FY 2003 TEFRA payments estimated on the basis of FY 2002 discharges would amount to a comparison between payments related to two different sets of discharges, potentially skewing the results. Therefore, for the purpose of consistency, rather than comparing TEFRA payments based on FY 2002 costs updated to FY 2003, to aggregate LTCH PPS payments for discharges that actually occurred in FY 2003, it would be preferable to compare estimated TEFRA payments based on updated FY 2002 costs to the estimated payments that would have been made under LTCH PPS methodology in FY 2003 for those same FY 2002 discharges.

In this proposed rule, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we are proposing to base our estimate of FY 2003 LTCH PPS payments on the same set of discharges (from FY 2002) which are the basis for the estimate of what would have been paid in FY 2003 under the reasonable cost-based (TEFRA) payment system. Specifically we are proposing to compare—

- Estimated aggregate FY 2003 TEFRA payments calculated on the basis of FY 2002 costs updated to FY 2003; to

• Estimated aggregate payments that would have been made in FY 2003 under the LTCH PPS methodology, by applying the FY 2003 LTCH payment rules to the discharges that occurred in FY 2002.

We believe that this approach would ensure that we are comparing the estimated FY 2003 TEFRA payments, which are based on updated costs incurred for FY 2002 discharges, to the estimated PPS payments that would have been made for those same FY 2002 discharges under the new LTCH PPS payment methodology. (We note that this is the same methodology for evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations that we presented in the RY 2009 LTCH PPS proposed and final rules (73 FR 5356 and 73 FR 26802, respectively).)

Under our proposal to use FY 2002 LTCH costs as a basis for estimating FY 2003 LTCH TEFRA payments in evaluating whether to propose a one-time prospective adjustment under § 412.523(d)(3), we are proposing to update LTCHs' FY 2002 costs for inflation to FY 2003 by our Office of the Actuary's current estimate of the actual increase in the excluded hospital market basket from FY 2002 to FY 2003 of 4.2 percent. This updated amount would serve as the proxy for actual FY 2003 costs under the TEFRA payment system in the proposed budget neutrality computation for purposes of the one-time prospective adjustment at § 412.523(d)(3). We note that when estimating reasonable cost-based payments under the TEFRA payment system, under our proposed methodology we updated LTCHs' TEFRA target amounts from FY 2002 to FY 2003 using the forecasted market basket percentage increase of 3.5 percent, as discussed in greater detail below. This approach maintains consistency with the approach taken in the FY 2003 IPPS final rule in which we established an applicable rate-of-increase percentage to update TEFRA target amounts from FY 2002 to FY 2003 of 3.5 percent (67 FR 50289). This increase was based on our Office of the Actuary's forecasted increase in the excluded hospital market basket for FY 2003, using the best available data at that time. Based on more recent data, our Office of the Actuary now estimates the actual increase in the excluded hospital market based from FY 2002 to FY 2003 is 4.2 percent (as stated above). We believe it is appropriate to propose to use the current estimate of the actual increase in the excluded hospital market basket based from FY 2002 to FY 2003 (4.2 percent) to update LTCHs' FY 2002 costs for inflation to FY 2003 because this reflects the most recent estimate of increases in the prices of goods and services realized by LTCHs when providing inpatient hospital services.

Our proposed methodology to estimate FY 2003 LTCH payments under the TEFRA payment system is similar in concept to the methodology we used to estimate FY 2003 LTCH total payments under the TEFRA payment system when we determined the initial standard Federal rate in the August 30, 2002 final rule (67 FR 56030 through 56033). We note that our proposed methodology for estimating FY 2003 LTCH total payments under the TEFRA payment system using FY 2002 cost data for the purposes of the one-time prospective adjustment at § 412.523(d)(3), includes modifications to the methodology we used to estimate FY 2003 LTCH total payments under the TEFRA system when we implemented the LTCH PPS because we are using data from a later period (FY 2002 as compared to FYs 1998 and 1999), as discussed in greater detail below. In general, we are proposing to estimate total LTCH payments under the TEFRA payment system in FY 2003 using the following steps:

• Estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003, including continuous bonus improvement payments (proposed step 1);

• Estimate each LTCH's payment per discharge for capital-related costs for FY 2003 (proposed step 2); and

• Sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge (proposed step 3).

We discuss each of these proposed steps in greater detail below.

Proposed Step 1.—Estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003.

Under our proposed methodology, the first step in the process of estimating total FY 2003 payments under the TEFRA payment system would be to estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system. Until FY 1998, the payment methodology for inpatient operating costs under the TEFRA payment system was a relatively straightforward process. First, we calculated a target amount by dividing the Medicare total allowable inpatient operating costs in a base year by the number of Medicare discharges. The provider's target amount under the TEFRA payment system (referred to as the TEFRA target amount) was then updated by a rate-of-increase percentage (§ 413.40(c)(3) of the regulations to determine the TEFRA target amount for the subsequent cost reporting period (§ 413.40(c)(4)(i) and(ii)). Generally, for any particular cost reporting period, the Medicare payment for inpatient operating costs would be the lesser of the hospital's allowable net inpatient operating costs, or the updated TEFRA target amount multiplied by the number of Medicare discharges during the cost reporting period, that is, the TEFRA ceiling (§ 413.40(a)(3)).

The TEFRA payment system methodology described above, broadly speaking, is the general approach that we are proposing to use to arrive at an estimate of what Medicare payments for hospital inpatient operating costs would have been in FY 2003 under the TEFRA payment system. That is, under our proposed methodology, each LTCH's FY 2003 TEFRA target amount would be calculated by updating its estimated FY 2002 target amount per discharge by the full market basket percentage increase. The sum of all LTCH payments for operating costs (TEFRA target amount multiplied by Medicare discharges), bonus or relief payments, continuous improvement bonus payments, and payments for capital-related costs yields, in general, the estimate of what total Medicare payments to LTCHs would have been in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented.

However, because sections 4413 through 4419 of the BBA of 1997, section 122 of the BBRA of 1999, and section 307(a)(1) of the BIPA made numerous changes to the TEFRA payment system, our proposed methodology reflects variations in the method described above to arrive at the estimate of FY 2003 payments for the inpatient operating costs of each LTCH under the TEFRA payment system, depending on the participation date of the hospital. Specifically, we are proposing to make the requisite computations differently for two classes of hospitals, ''existing'' hospitals and ''new'' hospitals. (A detailed explanation of the provisions affecting LTCHs, established by each of the amendments, is found in the August 30, 2002 final rule that implemented the LTCH PPS (67 FR 55959).) We discuss below these specific BBA, BBRA, and BIPA changes, and their impact on the calculations of estimated FY 2003 TEFRA payments for ''existing'' and ''new'' hospitals under our proposed methodology for estimating total LTCH payments under the TEFRA payment

system in FY 2003 for purposes of the one-time prospective adjustment under § 412.523(d)(3). As discussed in greater detail below, we are proposing to employ two approaches to estimate Medicare payments under the TEFRA payment system to LTCHs in FY 2003, depending on how these changes in calculating TEFRA payments, as established by the amendments, applied to each LTCH. (We note, the discussion below of the specific BBA, BBRA, and BIPA changes and their impact on the calculations of estimated FY 2003 TEFRA payments for ''existing'' and ''new'' hospitals under our proposed methodology for estimating total LTCH payments under the TEFRA payment system in FY 2003 for purposes of the one-time prospective adjustment under § 412.523(d)(3) is the same as the discussion presented in the RY 2009 LTCH PPS proposed rule (73 FR 5356 through 5359).)

The first set of changes that we would take into account was included in the BBA. The BBA made significant changes to the TEFRA payment methodology starting with cost reporting periods beginning on or after October 1, 1997. While the changes were applicable to three types of PPS-excluded providers (rehabilitation hospitals and units, psychiatric hospitals and units, and LTCHs), the following discussion will address the provisions of the amendments as they relate to LTCHs.

The first change to consider under the BBA is section 4414 that established caps on the TEFRA target amounts for cost reporting periods beginning on or after October 1, 1997, for LTCHs that were paid as IPPS-excluded providers prior to that date. The cap was determined by taking the 75th percentile of target amounts for cost reporting periods ending in FY 1996 for each class of provider (rehabilitation hospitals and units, psychiatric hospitals and units, and LTCHs), updating that amount by the market basket percentage increases to FY 1998, and applying it to the cost reporting period beginning on or after October 1, 1997 (62 FR 46018). The cap calculated for FY 1998 was updated by the applicable market basket percentages for cost reporting periods beginning during FY 1999 through 2002. Providers subject to the 75th percentile cap were paid the lesser of their inpatient operating costs or the TEFRA target amount, which was limited by the 75th percentile cap amount (67 FR 55959). In addition, section 4411 of the BBA established a formula for calculating the update factor for FY 1999 through FY 2002 that was dependent on the relationship of a provider's inpatient operating costs to its ceiling amount based on data from the most recently available cost report. Section 121 of the BBRA provided that the 75th percentile cap amount should be wage adjusted, starting with cost reporting periods beginning on or after October 1, 1999, and before October 1, 2002.

The second change that we would take into account was section 4415 of the BBA. This provision revised the percentage factors used to determine the amount of bonus and relief payments for LTCHs meeting specific criteria. If a provider's net inpatient operating costs did not exceed the hospital's ceiling, a bonus payment was made to the LTCH (§ 413.40(d)(2) of the regulations). The bonus payment was the lower of 15 percent of the difference between the hospital's inpatient operating costs and the ceiling, or 2 percent of the ceiling. In addition, relief payments were made to providers whose net inpatient operating costs were greater than 110 percent of the ceiling (or adjusted ceiling, if applicable). These relief payments were the lower of 50 percent of the allowable inpatient operating costs in excess of 110 percent of the ceiling (or the adjusted ceiling, if applicable) or 10 percent of the ceiling (or adjusted ceiling, if applicable) (§ 413.40(d)(3)(ii) of the regulations).

The third change that should be considered would be the additional incentive established by section 4415 of the BBA, the CIB payment for providers meeting certain conditions and that kept their costs below the target amount. Eligibility for the CIB payment required that a provider had three full cost reporting periods as an IPPS-excluded provider prior to the applicable fiscal year (62 FR 46019). To qualify for a CIB payment, a provider's operating costs per discharge in the current cost reporting period had to be lower than the least of any of the following: its target amount; its expected costs, that is, the lower of its target amount or allowable inpatient operating costs per discharge from the previous cost reporting period, updated by the market basket percent increase for the fiscal year; or, its trended costs, that is, the inpatient operating costs per discharge from its third full cost reporting period, updated by the market basket percentage increase to the applicable fiscal year (62 FR 46019; § 413.40(d)(5)(ii)(B) of the regulations). For providers with their third or subsequent full cost reporting period ending in FY 1996, trended costs are the lower of their allowable inpatient operating costs per discharge or target amount updated forward to the current year (§ 413.40(d)(5)(ii)(A) of the regulations). The CIB payment equals the lesser of 50 percent of the amount by which the operating costs were less than expected costs, or 1 percent of the ceiling (§ 413.40(d)(4) of the regulations). Section 122 of the BBRA increased this percentage for LTCHs for FY 2001 to 1.5 percent of the ceiling, and beginning in FY 2002, to 2 percent of the ceiling (§ 413.40(d)(4)(ii) and (iii) of the regulations). The increase in the CIB payment percentage is not to be accounted for in the development and implementation of the LTCH PPS in accordance with section 307(a)(2) of BIPA.

The fourth change that we would take into account was section 4416 of the BBA, which significantly revised the payment methodology for ''new'' IPPS-excluded providers. This provision applies to three classes of providers—psychiatric hospitals and units, rehabilitation hospitals and units, and LTCHs—that were not paid as excluded hospitals prior to October 1, 1997. The payment amount for a new provider for the first 12-month cost reporting period is the lower of its Medicare inpatient operating cost per discharge or a limit based on 110 percent of the national median of target amounts for the same class of hospital for cost reporting periods ending in FY 1996, updated by the market basket percentage increases to the applicable period, and wage-adjusted. The payment limit in the second 12-month cost reporting period is the same 110 percent limit as for the first year (§ 413.40(f)(2)(ii)). A new provider's target amount would be established in its third cost reporting period by updating the amount paid in its second cost reporting period by the market basket percentage increase for hospitals and hospital units excluded from the IPPS, applicable to the specific year, as published annually in the **Federal Register**, which then becomes the target amount for its third cost reporting period. The target amount for the fourth and subsequent cost reporting periods is determined by updating the target amount from the previous cost reporting period by the applicable market basket percentage increase.

Finally, two provisions under BIPA specifically related to LTCHs. Section 307(a) of BIPA provided a 2 percent increase to the wage-adjusted 75th percentile cap for existing LTCHs for cost reporting periods beginning in FY 2001, and a 25 percent increase to the target amount for LTCHs, subject to the increased 75th percentile cap. However, it is important to note that in accordance with section 307(a)(2) of BIPA, the 2 percent increase to the 75th percentile cap and the 25 percent

increase to the target amount were not to be taken into account in the development and implementation of the LTCH PPS.

In this proposed rule, under our proposed methodology, in order to determine what a LTCH's estimated payments would be under the TEFRA payment system in FY 2003, we are proposing to use cost report data for LTCHs from the Hospital Cost Reporting Information System (HCRIS) for FYs 1999 through 2002. In addition, to determine whether a LTCH is ''new,'' the certification date for each LTCH was obtained from the On-line Survey & Certification Automated Reporting (OSCAR) file. Based on the certification date, a LTCH would either be a ''new'' LTCH, meaning a LTCH that was not paid as an excluded hospital prior to October 1, 1997, or, an ''existing'' LTCH, meaning a LTCH that was paid as an excluded hospital prior to October 1, 1997. This could include a LTCH that was certified as an LTCH on or after October 1, 1997, but was previously paid as another type of IPPS-excluded provider prior to October 1, 1997. Our proposed approach to estimating Medicare payments in FY 2003 under the TEFRA payment system would vary somewhat, depending on whether an LTCH was ''existing'' or ''new'' is discussed in greater detail below. Below we discuss our proposed methodology for estimating FY 2003 inpatient operating payments under the TEFRA payment system for ''existing'' hospitals (proposed Step 1.a.) and ''new'' hospitals (proposed Step 1.b.), and our proposed methodology for estimating CIB payments under the TEFRA payment system in FY 2003 (under proposed Step 1.c.).

Proposed Step 1.a.—Estimate FY 2003 inpatient operating payments under the TEFRA payment system for ''existing'' LTCHs.

Based on the applicable statutory changes mentioned above, under our proposed methodology, the first step would be to estimate FY 2003 inpatient operating payments under the TEFRA payment system for ''existing'' LTCHs. ''Existing'' LTCHs are those receiving payment as IPPS-excluded providers in cost reporting periods prior to FY 1998. These LTCHs were subject to the 75th percentile cap on their hospital-specific target amounts. While section 307(a)(1) of BIPA provided for a 2-percent increase to the 75th percentile cap amount for LTCH's for cost reporting periods beginning in FY 2001 and a 25-percent increase to the target amount for cost reporting periods beginning in FY 2001 (subject to the limiting or cap amount determined under section 1886(b)(3)(H) of the Act), section 307(a)(2) of BIPA precluded accounting for these increases in developing the LTCH PPS. In addition, section 122 of the BBRA increased the CIB payment percentage to 1.5 percent for FY 2001 and 2.0 percent for FY 2002 (§ 413.40(d)(4)(ii) and (iii)). But these increases, also, are not to be accounted for the development and implementation of the LTCH PPS in accordance with section 307(a)(2) of BIPA. Therefore, to ensure that these increases would be excluded from the computations, as required by the statute, we are proposing to estimate an existing LTCH's FY 2003 target amount by starting with the hospital's target amount from the FY 2000 cost report, the year prior to when these increases were effective. Target amounts and payments for FY 2003 would be simulated using the FY 2000 target amount in the hospital's cost report and updating the target amount for each subsequent cost reporting period by the applicable rate-of-increase percentage as described in § 413.40(c)(3)(vii) through FY 2002. The target amount from FY 2002 would be updated by the forecasted market basket percentage increase of 3.5 percent to arrive at the FY 2003 target amount (§ 413.40(c)(3)(viii)). (We note that the forecasted increase in the excluded hospital market basket for FY 2003 of 3.5 percent would be used to establish the applicable rate-of-increase percentage used to update TEFRA target amounts in accordance with § 413.40(c)(3)(viii) in the FY 2003 IPPS final rule (67 FR 50289)). Based on more recent data, our Office of the Actuary currently estimates an increase of 4.2 percent in the excluded hospital market basket for FY 2003, which we are proposing to use to update LTCHs' FY 2002 costs to FY 2003, as described below.) In a small number of cases where FY 2002 operating cost data were not available, we would use operating cost data from the most recent year available and trend it forward to FY 2003. In addition, we would estimate FY 2003 bonus or relief payments without the inclusion of the 2-percent and 25-percent increases to the cap amount and target amount, respectively, and without the 1.5 percent and 2.0 percent increases to the CIB payments, consistent with section 307(a)(2) of BIPA as discussed above.

In addition, because comparisons are made between the target amount and Medicare inpatient operating costs to determine bonus or relief payments, under our proposed methodology, we would estimate FY 2003 operating costs for each LTCH by updating its FY 2002 operating costs by the actual percentage increase in operating costs for PPS-excluded hospitals from FY 2002 to FY 2003 (4.2 percent, as determined by our Office of the Actuary) because this is currently our best estimate of actual cost increase from FY 2002 to FY 2003 realized by excluded hospitals, including LTCHs. As discussed earlier, we are proposing to estimate the FY 2003 operating costs using FY 2002 costs rather than using the costs reported on the FY 2003 cost report.

The 75th percentile cap for LTCHs for FY 2002, without the 2-percent and 25-percent increases to the cap and target amount, respectively, was $30,783 for the wage-index adjusted labor-related share, and $12,238 for the nonlabor-related share. If a LTCH's costs and hospital-specific target amount were above the 75th percentile cap, Medicare's payment under the TEFRA system would be the wage-index adjusted cap amount. If under our proposed payment model a LTCH's estimated FY 2002 TEFRA payment would have been limited by the wage-adjusted 75th percentile cap in FY 2002, that amount would be updated by the forecasted market basket percentage increase (of 3.5 percent) to FY 2003 to determine the LTCH's FY 2003 target amount that was used to estimate its TEFRA payment system amount for FY 2003 under our proposed methodology.

Proposed Step 1.b.—Estimate FY 2003 inpatient operating payments under the TEFRA payment system for ''new'' LTCHs.

Next, under our proposed methodology, we would estimate FY 2003 hospital operating payments under the TEFRA payment system applied to ''new'' LTCHs based on the applicable statutory changes discussed above. A ''new'' LTCH is one that was first paid as an IPPS-excluded hospital on or after October 1, 1997. For a ''new'' LTCH, payment in the hospital's first 12-month cost reporting period is the lower of its Medicare net inpatient operating costs per discharge or the wage-adjusted 110 percent median amount determined for that particular year (§ 413.40(f)(2)(ii) of the regulations). For the hospital's second 12-month cost reporting period, payment is the lower of their costs, or the same 110 percent median amount that was used in the first cost reporting period, that is, it is not updated. The hospital's ''target amount'' is established in the third cost reporting period by updating the per discharge amount that was paid in the prior cost reporting period by the estimated market basket percentage increase for hospitals and hospital units excluded from the IPPS,

applicable to the specific year, as published annually in the **Federal Register**. Therefore, if the LTCH was paid its costs in the previous cost reporting period because costs were lower than the 110 percent median amount, the hospital's cost per discharge for the second cost reporting period is updated and becomes the target amount for the hospital's third cost reporting period. Target amounts for subsequent cost reporting periods are determined by updating the previous year's target amount by the applicable market basket percentage increase.

New LTCHs with their first 12-month cost reporting period beginning in FY 1998 would have had a target amount calculated under section 1886(b)(7)(A)(ii) of the Act in FY 2000. Therefore, consistent with our proposals concerning ''existing'' LTCHs (described in proposed Step 1.a. above), in estimating the FY 2003 target amount for ''new'' LTCHs we are proposing to use the target amount from the FY 2000 cost report and update that target amount by the applicable estimated market basket percentage increases as published annually in the **Federal Register** for the IPPS final rule, without the 25-percent increase, to FY 2003. That is, we used 3.4 percent to update from FY 2000 to FY 2001, 3.3 percent to update from FY 2001 to FY 2002, and 3.5 percent to update from FY 2002 to FY 2003. For LTCHs with their first 12-month cost reporting period beginning in FY 1999, we would use the lower of their costs or target amount from their FY 2000 cost report, and updated that amount by the applicable estimated market basket percentage increase to establish the target amount in FY 2001, without the 25-percent increase. Next, we would continue to update that target amount by the estimated market basket percentage increases to FY 2003. We believe that it is necessary to propose to compute an estimated target amount for LTCHs that are ''new'' in FY 1999 under our proposed methodology in order to eliminate the potential inclusion of the increase to the target amounts provided for by section 307(a)(1) of BIPA (consistent with the statute).

The 25-percent increase (under section 307(a) of the BIPA) to the target amount would not be an issue for LTCH's with their first 12-month cost reporting period beginning in FYs 2000, 2001, and 2002 because they would not have a ''target amount'' based on sections 1886(b)(7)(A)(ii) of the Act, in FY 2001. Rather, for these LTCHs, under our proposed methodology we would determine the estimated payment amount for their first 12-month cost reporting period by looking at their certification date from the OSCAR file, the applicable 110 percent median amount (adjusted by their wage-index) and their costs from the applicable cost report, and then proceed in accordance with the policy in § 413.40(f)(2)(ii) of the regulations, to arrive at estimated FY 2003 TEFRA payments.

Proposed Step 1c.—Estimate CIB payments that would have been made in FY 2003 under the TEFRA payment system (for both ''existing'' and ''new'' LTCHs).

In addition to the TEFRA system payments for operating costs, and any bonus or relief payments made, we also are proposing to add an amount to account for the estimate of the CIB payments that would have been made in FY 2003 under the TEFRA payment system under § 413.40(d)(4). We are proposing to estimate what CIB payments would have been in FY 2003 by using actual CIB payments from the cost reports for FYs 1999 and 2000, as they would not include the statutory increases to the target amount discussed above, and recalculated CIB payments for FYs 2001 and 2002 based on cost report data. Based on these historical CIB payments, we estimated that CIB payments in FY 2003 would have been approximately $10 million. Just as the TEFRA payments and bonus and relief payments had to be recalculated in particular years to eliminate percentage increases that are not to be included in our budget neutrality calculations (as required by the statute), we believe that it is necessary to propose to recalculate the CIB payments in FYs 2001 and 2002 to eliminate the percentage increases to these payments as provided for under section 122 of BBRA, such that they would not be accounted for in the development of the LTCH in accordance with section 307(a)(2) of BIPA. Therefore, under our proposed methodology, we are proposing to add $10 million as an estimate of the CIB payments that would have been made in FY 2003 under the TEFRA payment system to our estimated FY 2003 TEFRA system payments for operating costs, including any bonus or relief payments.

Step 2.—Estimate each LTCH's payment per discharge for inpatient capital costs under the TEFRA payment system for FY 2003.

As we discussed above, under our proposed methodology, the second step in estimating total payments under the TEFRA payment system is to estimate each LTCH's payment per discharge for capital-related costs for FY 2003. Under the TEFRA payment system, in accordance with the regulations at 42 CFR Part 413, Medicare allowable capital costs are paid on a reasonable cost basis. Therefore, we are proposing to update each LTCH's payment for capital-related costs directly from the FY 2002 cost report for inflation using the FY 2003 capital excluded hospital market basket estimate of 0.7 percent, consistent with the methodology used to establish the initial standard Federal rate (67 FR 56031). Thus, we are proposing to determine capital-related costs per case using capital cost data from Worksheets D, Parts I and II, and total Medicare discharges for the cost reporting period from Worksheet S–3. (We note that since payments for capital-related costs are on a reasonable-cost basis, capital payments were the same for ''existing'' and ''new'' LTCHs.)

Proposed Step 3.—Sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge.

Under our proposed methodology for estimating FY 2003 LTCH total payments under the TEFRA payment system using FY 2002 cost data for the purposes of the one-time prospective adjustment at § 412.523(d)(3), after estimating payments for inpatient operating costs under the TEFRA payment system for FY 2003 and payments for capital-related costs under the TEFRA payment system for FY 2003, we would sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge. Therefore, we are proposing to add the estimate of each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003, including continuous improvement bonus payments (determined under proposed Steps 1.a. through 1.c. above) and the estimate of each LTCH's payment per discharge for capital-related costs for FY 2003 (determined under proposed Step 2 above).

Once we estimate total TEFRA payments as the sum of each LTCH's estimated operating and capital payment per case, under our proposed methodology for evaluating the one-time prospective adjustment at § 412.523(d)(3), the next step is to estimate FY 2003 payments under the LTCH PPS. As we discussed above, we believe that the best approach is to propose to use FY 2002 LTCH claims data as a proxy for estimating FY 2003 LTCH PPS payments in evaluating the one-time prospective adjustment at § 412.523(d)(3). We note that we are proposed to use the same FY 2002 LTCH MedPAR data that was used to

develop the FY 2004 LTC–DRG relative weights in the FY 2004 IPPS final rule (68 FR 45376), as explained below. As we discussed in that final rule, there is a data problem with the FY 2002 claims data for LTCHs where multiple bills for the stay were submitted. Specifically, given the long stays at LTCHs, some providers had submitted multiple bills for payment under the reasonable cost-based reimbursement system for the same stay. In certain LTCHs, hospital personnel apparently reported a different principal diagnosis on each bill because, under the reasonable cost-based (TEFRA) reimbursement system, payment was not dependent upon principal diagnosis, as it is under a DRG-based PPS system. As a result of this billing practice, we discovered that only data from the final bills were being extracted for the MedPAR file. Therefore, it was possible that the original MedPAR file was not receiving the correct principal diagnosis. In that same IPPS final rule, we discussed how we addressed this problem in the LTCH FY 2002 MedPAR data when we used that data to determine the FY 2004 LTC–DRG relative weights. Therefore, for the evaluation of the one-time prospective adjustment at § 412.523(d)(3) in this proposed rule, we are proposing to use the same ''corrected'' FY 2002 LTCH MedPAR data that was used to develop the FY 2004 LTC–DRG relative weights. For the reader's benefit, we are providing a summary of how we addressed the multiple bill problem in the FY 2002 LTCH MedPAR data below. As we explained in the FY 2004 IPPS final rule (68 FR 45376), we addressed this problem by identifying all LTCH cases in the FY 2002 MedPAR file for which multiple bills were submitted. For each of these cases, beginning with the first bill and moving forward consecutively through subsequent bills for that stay, we recorded the first unique diagnosis codes up to 10 and the first unique procedure codes up to 10. We then used these codes to appropriately group each LTCH case to a LTC–DRG for FY 2004. (We note that this is the same data we used to estimate FY 2003 payments under the LTCH PPS for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule (73 FR 5359).)

In this proposed rule, we are proposing to estimate FY 2003 LTCH PPS payments using the same general methodology that we used to estimate FY 2003 payments under the LTCH PPS (without a budget neutrality adjustment) when we determined the initial standard Federal rate in the August 30, 2002 final rule (67 FR 56032). Specifically, we are proposing to estimate FY 2003 LTCH PPS payments for each LTCH by simulating payments on a case-by-case basis by applying the final FY 2003 payment policies established in the August 30, 2002 final rule that implemented the LTCH PPS (67 FR 55954) based on the LTCH case-specific discharge information from the FY 2002 MedPAR files (as explained above), and we also are proposing to use LTCH provider-specific data from the FY 2003 Provider-Specific File (PSF), as these were the data used by fiscal intermediaries to make LTCH payments during the first year of the LTCH PPS (FY 2003). Under our proposed methodology, we are proposing to use the FY 2003 LTC–DRG Grouper (Version 22.0), relative weights, and average length of stay (67 FR 55979 through 55995); we are proposing to make adjustments for differences in area wage levels established for FY 2003 as set forth at § 412.525(c) using the appropriate phase-in wage index values for FY 2003 (67 FR 56015 through 56020); we are proposing to make a cost-of-living adjustment for LTCHs located in Alaska and Hawaii as set forth at § 412.525(b) (67 FR 56022); we are proposing to make adjustments for SSO cases based on the method for determining payment applicable for discharges occurring during FY 2003 in accordance with § 412.529(c)(1) (67 FR 55975 and 55995 through 56002); and we are proposing to include additional payments for HCO cases in accordance with former § 412.525(a) for determining payments for discharges occurring in FY 2003 and the FY 2003 fixed-loss amount of $24,450 (67 FR 56023). (We note that correctly billed interrupted stay cases under § 412.531 are single LTCH cases in the MedPAR files; therefore, we estimated a single LTCH PPS payment for those cases.) Under this proposed methodology, for purposes of this calculation we are proposing to simulate case-by-case payments for each LTCH as if it were paid based on 100 percent of the standard Federal rate in FY 2003 rather than the transition blend methodology set forth at § 412.533. To determine total estimated PPS payments for all LTCHs, we are proposing to sum the individual estimated LTCH PPS payments for each LTCH. (We note that this is the same methodology we used to estimate FY 2003 payments under the LTCH PPS for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule (73 FR 5359 through 5360).)

In order to determine if there is any difference between estimated total TEFRA payments and estimated LTCH PPS payments in FY 2003 under our proposed methodology for evaluating a possible one-time prospective adjustment under § 412.523(d)(3), we are proposing to determine a case-weighted average estimated TEFRA payment, consistent with the methodology used when we determined the initial standard Federal rate in the FY 2003 LTCH PPS final rule (68 FR 56032). Under this proposed methodology, each LTCH's estimated total FY 2003 TEFRA payment per discharge would be determined by summing its estimated FY 2003 operating and capital payments under the TEFRA payment system based on FY 2002 cost report data (as described in proposed Step 3 above), and dividing that amount by the number of discharges from the FY 2002 cost report data. Next, we would determine each LTCH's average estimated TEFRA payment weighted for its number of discharges in the FY 2002 MedPAR file (for the purpose of estimating FY 2003 LTCH PPS payments, as discussed above) by multiplying its average estimated total TEFRA payment per discharge by its number of discharges in the FY 2002 MedPAR file. We would then estimate total case-weighted TEFRA payments by summing each LTCH's (MedPAR) case-weighted estimated FY 2003 TEFRA payments. Under our proposed methodology, we are proposing to compare these estimated FY 2003 total TEFRA payments to estimated FY 2003 total LTCH PPS payments in order to determine whether a one-time prospective adjustment would be appropriate. (As discussed in greater detail above, we are proposing to determine both estimated total FY 2003 TEFRA payments and estimated total FY 2003 LTCH PPS payments based on FY 2002 cost report and claims data, respectively.) Our proposal to adjust our proposed estimate of FY 2003 TEFRA payments for the number of discharges that we are proposing to use to estimate FY 2003 LTCH PPS payments would ensure that the comparison of estimated aggregate FY 2003 TEFRA payments to estimated aggregate FY 2003 LTCH PPS payments would be based on the same number of LTCH discharges. (We note that this is the same methodology we used to compare estimated FY 2003 total TEFRA payments to estimated FY 2003 total LTCH PPS payments for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the

RY 2009 LTCH PPS proposed rule (73 FR 5360).)

For this proposed rule, using the proposed methodology and data described above, we have calculated that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated payments to the same LTCHs in FY 2003 if the LTCH PPS had not been implemented (that is, estimated total FY 2003 TEFRA payment system payments). This analysis was based on approximately 91,300 LTCH discharges for 250 LTCHs. As discussed above, we are proposing that any difference greater than or equal to 0.25 percentage points that is ''significant'' for purposes of determining whether the one-time prospective adjustment provided under § 412.523(d)(3) would be warranted. Although we project that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated FY 2003 TEFRA payments, proposing to reduce the standard Federal rate by 2.5 percent would not ''maintain budget neutrality'' for FY 2003 (that is, estimated FY 2003 LTCH PPS payments would not be equal to estimated FY 2003 TEFRA payments) because a considerable number of LTCH discharges are projected to have received a LTCH PPS payment in FY 2003 based on the estimated cost of the case (rather than a payment based on the standard Federal rate) under the payment adjustment for SSO cases at § 412.529. Specifically, under our proposed methodology our payment analysis indicates that nearly 20 percent of estimated FY 2003 LTCH PPS payments are SSO payments that were paid based on estimated cost and not based on the LTCH PPS standard Federal rate. These SSO cases that receive a payment based on the estimated cost of the case are generally unaffected by any changes to the standard Federal rate because the estimated cost of the case is determined by multiplying the Medicare allowable charges by the LTCH's cost-to-charge ratio (§ 412.529(d)(2)). In other words, if we were to propose to reduce the standard Federal rate by 2.5 percent, estimated total FY 2003 LTCH PPS payments would still be greater than estimated total FY 2003 TEFRA payments (that is, would not be budget neutral), and this difference would be perpetuated in the LTCH PPS payment rates for future years. This is because the estimated LTCH PPS payments for those SSO cases that in FY 2003 were estimated to have been paid 120 percent of the estimated cost of the case generally are not affected (that is, in this case, not lowered) by any one-time prospective adjustment budget neutrality factor that would be applied to the standard Federal rate because those payments are not derived from the standard Federal rate (as explained above). Therefore, it is necessary to propose to offset the standard Federal rate by a factor that is larger than 2.5 percent in order to ensure that estimated total FY 2003 LTCH PPS payments would be equal to estimated total FY 2003 TEFRA payments in order to ''maintain budget neutrality.'' To determine the necessary adjustment factor that would need to be applied to the standard Federal rate in order to ''maintain budget neutrality,'' we are proposing to simulate FY 2003 LTCH PPS payments using the same payment simulation model discussed above (that we proposed to use to estimate FY 2003 LTCH PPS payments without a budget neutrality factor). Using iterative payment simulations using the data from the 250 LTCHs in our database, we determined that we would need to apply a factor of 0.9625 (that is, a reduction of approximately 3.75 percent rather than 2.5 percent) to the standard Federal rate in order to make estimated total FY 2003 LTCH PPS payments equal to estimated total FY 2003 TEFRA payments consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3) (that is, to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years). (We note that this proposed adjustment of approximately −3.75 percent is the same result of the evaluation of the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed and final rules (73 FR 5360 and 26804, respectively).) As we note in the RY 2009 LTCH PPS proposed and final rules, in the years following the initial implementation of the LTCH PPS, we have adopted some revised policies and adjustments to LTCH PPS payment levels. However, none of these revised policies and payment adjustments have addressed the intended purpose of the one-time prospective adjustment allowed under § 412.523(d)(3) of the regulations, to ensure that any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 are not perpetuated in the LTCH PPS rates for future years. For example, the adjustments that we have made to account for coding changes in excess of real severity increases in RYs 2007 through 2010 were made to account for changes in coding behavior in the years following the implementation of the LTCH PPS, and not to address any issue regarding the budget neutrality calculations that were used to establish the base rate for the LTCH PPS.

In this proposed rule, based on the proposed methodology described above, under the broad authority granted to the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to revise § 412.523(d)(3) to specify that the standard Federal rate would be permanently reduced by 3.75 percent so that the estimated difference between projected aggregate LTCH PPS payments in FY 2003 and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented. Consistent with current law, we also are proposing that this adjustment would not apply to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012. Furthermore, given the magnitude of this adjustment and in acknowledgement of hopeful research outcomes (discussed above in section VII.E.2. of this preamble), we are proposing to phase-in this approximate 3.75 percent reduction to the standard Federal rate over a 3-year period. Although the adjustment to the standard Federal rate provided for at § 412.523(d)(3) is called a ''one-time'' prospective adjustment, as stated above, this proposed adjustment would be permanently applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years. During this proposed 3-year period, we intend to further explore potential revisions to certain LTCH PPS payment policies as discussed above in section VII.E.2. of this preamble. Under this proposal, we would make a one-time prospective adjustment by applying a factor of 0.98734 to the standard Federal rate in FY 2013 (which would not be applicable to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, consistent with current law), FY 2014 and FY 2015 to completely account for our estimate (determined using the proposed methodology described above) that a factor of 0.9625 (that is 0.98734

× 0.98734 × 0.98734 = 0.9625) needs to be applied to the standard Federal rate in order to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3). In other words, we are proposing that in determining the standard Federal rate in each year for FYs 2013 through 2014, we would multiply the standard Federal rate otherwise determined in absence of the one-time prospective adjustment at § 412.523(d)(3) by 0.98734 in order to ensure that the estimated difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years.

VIII. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

CMS is seeking to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of an increasing number of widely agreed-upon quality measures. CMS has worked with relevant stakeholders to define measures of quality for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

CMS has implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, CMS implemented the Hospital Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). In addition, CMS has implemented quality reporting programs for hospital outpatient services, the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)), and for physicians and other eligible professionals, the Physician Quality Reporting System (formerly referred to as the Physician Quality Reporting Program Initiative (PQRI)). CMS has also implemented quality reporting programs for inpatient rehabilitation hospitals, hospices, and ambulatory surgical centers, and an end-stage renal disease quality improvement program (76 FR 628 through 646) that links payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, so that the electronic collection of performance information is part of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructural development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that automatic collection and reporting of data elements for many measures through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs and that at a future date, such as FY 2015, hospitals will be able to switch primarily to EHR-based reporting of data for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We have also implemented a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. In 2011, we issued the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We adopted additional policies for the Hospital VBP Program in section IV.B. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660) and in section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547). Under the Hospital VBP Program, hospitals will receive value-based incentive payments if they meet performance standards with respect to measures for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework of the Hospital VBP Program. Section 1886(o)(2)(B)(i)(I) of the Act states that for FY 2013, the selected measures for the Hospital VBP Program must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), surgical care, as measured by the Surgical Care Improvement Project (SCIP), and Healthcare-Associated Infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs (or any successor HHS plan). Section 1886(o)(2)(B)(i)(II) of the Act provides that, for FY 2013, measures selected for the Hospital VBP Program must also be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

The Hospital IQR Program is linked with the Hospital VBP Program because the measures and reporting infrastructure for both programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare into an active purchaser of quality healthcare for its beneficiaries. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), we applied the following principles for the development and use of measures and scoring methodologies:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of

measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

- The collection of information should minimize the burden on providers to the extent possible. As part of this effort, we will continuously seek to align our measures with the adoption of e-specified measures, so the electronic collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multistakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized by section 3008 of the Affordable Care Act and the Hospital VBP Program as being related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance, while the program established by section 3008 of the Affordable Care Act creates a payment adjustment resulting in payment reductions for the lowest performing hospitals based on their rates of HACs.

Although we intend to monitor the various interactions of programs authorized by the Affordable Care Act and their overall impact on providers and suppliers, we also view programs that could potentially affect a hospital's Medicaid payment as separate from programs that could potentially affect a hospital's Medicare payment.

In this section VIII. of this proposed rule, we are proposing changes to, or implementing, the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program.
- In section VIII.B., the Hospital VBP Program.
- In section VIII.C., the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.
- In section VIII.D., the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.
- In section VIII.E., the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.
- In section VIII.F., the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of Measures Adopted for the Hospital IQR Program

We refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636 through 51637) for the measures we have adopted for the Hospital IQR measure set through FY 2015.

b. Maintenance of Technical Specifications for Quality Measures

The technical specifications for the Hospital IQR Program measures, or links to Web sites hosting technical specifications, are contained in the CMS/The Joint Commission (TJC) Specifications Manual for National Hospital Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at *https://www.QualityNet.org.* We generally update the Specifications Manual on a semiannual basis and include in the updates detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS *Quality Assurance Guidelines* manual, which is available at the HCAHPS On-Line Web site, *http://www.hcahpsonline.org.* We maintain the HCAHPS technical specifications by updating the HCAHPS *Quality Assurance Guidelines* manual annually, and include detailed instructions on survey implementation, data collection, data submission and other relevant topics. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the Hospital IQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the QualityNet Web site at *https://www.QualityNet.org.* We would provide sufficient lead time for hospitals to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to a measure that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to

incorporate NQF updates to NQF-endorsed Hospital IQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608 through 51609), we adopted a policy to display information regarding the measures (such as names of measures for which data will be displayed in the future) on the *Hospital Compare* Web site under this provision. We will continue our current practice of reporting data from the Hospital IQR Program as soon as it is feasible on CMS Web sites such as the *Hospital Compare* Web site, *http://www.hospitalcompare.hhs.gov,* after a 30-day preview period.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish. The Hospital IQR Program currently includes process of care measures, risk-adjusted outcome measures, the HCAHPS patient experience-of-care survey, structural measures, Emergency Department Throughput timing measures, hospital acquired condition measures, immunization measures, and hospital acquired infection measures, all of which are featured on the *Hospital Compare* Web site.

However, information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations for inclusion on *Hospital Compare* may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as *http://www.cms.hhs.gov/HospitalQualityInits/*. Publicly reporting the information in this manner, although not on the *Hospital Compare* Web site, allows CMS to meet the requirement under section 1886(b)(3)(B)(viii)(VII) of the Act for establishing procedures to make information regarding measures submitted under the Hospital IQR Program available to the public following a preview period. In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts and memorandums, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than *Hospital Compare.*

2. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures From the Hospital IQR Program

We generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when they are removed or replaced as indicated. In previous rulemakings, we have referred to the removal of measures from the Hospital IQR Program as ''retirement.'' We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, beginning with this rulemaking cycle, we will use the term ''remove'' rather than ''retire'' to refer to the action of no longer including a measure in the Hospital IQR Program.

As we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), the criteria that we consider when determining whether to remove Hospital IQR Program measures are the following: (1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and, (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested by commenters during rulemaking, and we agreed that these criteria should be among those considered in evaluating Hospital IQR Program quality measures for removal.

Additionally, we take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay for reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

b. Hospital IQR Program Measures Removed in Previous Rulemakings

In previous rulemakings, we have removed several Hospital IQR Program quality measures, including:

- PN–1: Oxygenation Assessment for Pneumonia, a ''topped out'' measure, because measures with very high performance among hospitals present little opportunity for improvement and do not provide meaningful distinctions in performance for consumers (73 FR 48604).
- AMI–6: Beta Blocker at Arrival measure from the Hospital IQR Program because it no longer ''represent[ed] the best clinical practice,'' as required under section 1886(b)(3)(B)(viii)(VI) of the Act. We stated that when there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, it is appropriate for CMS to take immediate action to remove a measure from the Hospital IQR Program and not wait for the annual rulemaking cycle. Therefore, we adopted the policy (74 FR 43864 and 43865) that we would promptly remove such a measure, confirm the removal in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly remove measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos, email notification, and QualityNet Web site postings.
- Mortality for Selected Procedures Composite measure because the measure is not considered suitable for

purposes of comparative reporting by the measure developer (75 FR 50186).

- Three adult smoking cessation measures: AMI–4: Adult Smoking Cessation Advice/Counselling; HF–4: Adult Smoking Cessation Advice/Counselling; and PN–4: Adult Smoking Cessation Advice/Counselling, because these measures are ''topped-out'' and no longer NQF-endorsed (76 FR 51611).
- PN–5c: Timing of Receipt of Initial Antibiotic Following Hospital Arrival measure out of concerns that the continued collection of this measure might lead to the unintended consequence of antibiotic overuse (76 FR 51611).

c. Proposed Removal of Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years

To accommodate the expansion of the measure set, we have considered the removal of additional Hospital IQR measures using our stated measure removal criteria. Based on some of these criteria, we are proposing to remove 17 measures from the Hospital IQR Program. One of these 17 measures is chart-abstracted, and the other 16 are claims-based.

(1) Proposed Removal of One Chart-Abstracted Measure

We are proposing to remove the SCIP–Venous Thromboembolism (VTE) measure: ''SCIP–VTE–1: Surgery patients with recommended VTE prophylaxis ordered'' measure because we believe that the ''SCIP–VTE–2: Surgery patients who received appropriate VTE prophylaxis within 24 hours of pre/post surgery'' measure currently used in the Hospital IQR Program assesses practices that are more proximal in time to better surgical outcomes resulting from the use of VTE prophylaxis. We also note that during a recent NQF maintenance review of SCIP–VTE–1, the measure was not recommended for continued endorsement.

(2) Proposed Removal of 16 Claims-Based Measures

We are proposing to remove eight HAC measures, three AHRQ Inpatient Quality Indicator (IQI) measures, and five AHRQ Patient Safety Indicator (PSI) measures from the Hospital IQR Program measure set.

(A) Proposed Removal of Eight Hospital-Acquired Condition (HAC) Measures

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50194 through 50196), for the FY 2012 payment determination, we adopted 8 claims-based HAC measures based on 8 of the 10 conditions applicable under the HAC payment provisions specified in section 1886(d)(4)(D) of the Act apply. These eight HAC measures are: Air Embolism; Blood Incompatibility; Catheter-Associated Urinary Tract Infection (UTI); Falls and Trauma: (Includes Fracture Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock); Foreign Object Retained After During Surgery; Manifestations of Poor Glycemic Control; Pressure Ulcer Stages III or IV; and Vascular Catheter Associated Infections. Six of these HACS were identified by NQF as serious reportable events.

We are proposing to remove these eight HAC measures based on several considerations. First, the MAP recommended that we replace the HAC measures in the Hospital IQR Program with NQF-endorsed measures. Second, we seek to reduce redundancy among the measures in the program. Two of the eight HAC measures address HAIs which are addressed by other measures currently in the Hospital IQR Program. These two HAI measures are the NQF-endorsed CAUTI and CLABSI measures collected via the CDC's NHSN system. An additional three of the eight HAC measures address similar topics (pressure ulcers, air embolism, and manifestations of poor glycemic control) to patient safety indicators that are included in the NQF-endorsed AHRQ PSI composite that is also included in the Hospital IQR Program. Accordingly, because more broadly applicable NQF-endorsed measures are available that address the same HAIs and HACs, we believe it is appropriate to remove these measures from the program. We note that section 3008 of the Affordable Care Act will require public reporting of HAC measures, including measures for conditions adopted under section 1886(d)(4)(D) of the Act. HACs remain an important aspect of our strong commitment to measure patient harm and safety. ''Safer care'' is one of the six priorities identified to address the three aims established under the National Quality Strategy. We intend to pursue development of an all-cause harm composite measure for potential use in our quality reporting programs.

(B) Proposed Removal of Three AHRQ IQI Measures

In the FY 2009 IPPS final rule (73 FR 48607), we adopted three claims-based AHRQ IQI outcome measures for the FY 2010 payment determination: (1) IQI–11: Abdominal aortic aneurysm (AAA) repair mortality rate (with or without volume); (2) IQI–19: Hip fracture mortality rate; and (3) IQI–91: Mortality for selected medical conditions (composite).

We are proposing to remove these three AHRQ IQI measures from the Hospital IQR Program. In removing measures from the Hospital IQR Program, we seek to eliminate measures that would not be used under the Hospital VBP Program, and to reduce redundancy among the measures in the Hospital IQR Program. Three of the six conditions in the IQI composite measure overlap with 30-day mortality measures that we have in the Hospital IQR Program, and which were recommended by the MAP for use in the Hospital VBP Program. The proposed removal of these AHRQ IQI measures would eliminate unnecessary redundancy in the Hospital IQR measure set. We also believe that inclusion of a large number of in-hospital mortality measures, the performance on which is highly dependent upon hospital discharge patterns, may lead to unintended consequences of patients being discharged sooner than advisable. We invite public comment on this proposal.

(C) Proposed Removal of Five AHRQ PSI Measures

In the FY 2009 IPPS final rule (73 FR 48607), we adopted three claims-based PSI outcome measures for the FY 2010 payment determination: (1) PSI–06: Iatrogenic pneumothorax; (2) PSI–14: Postoperative wound dehiscence; and (3) PSI–15: Accidental puncture or laceration. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50194), we adopted two more claims-based PSI outcome measures for the FY 2012 payment determination: PSI–11: Post Operative Respiratory Failure; and PSI 12: Post Operative PE or DVT.

We are proposing to remove these five AHRQ PSI measures from the Hospital IQR Program because four of these five individual measures (all but PSI 11) are included in the NQF-endorsed AHRQ PSI Composite measure that is already included in the Hospital IQR Program. Also, the post-operative ventilator associated events assessed in PSI–11 could be captured more robustly using non-administrative data collected via the NHSN in the near future. Therefore, we are proposing to remove these five individual PSIs from the Hospital IQR Program measure set in order to eliminate unnecessary redundancy. We invite public comment on this proposal.

In summary, for the FY 2015 payment determination and subsequent years, we are proposing to remove the SCIP–VTE–1 measure, eight HAC measures, three AHRQ IQI measures, and five AHRQ PSI measures from the Hospital IQR measure set. The list of measures we are

proposing to remove is set out in the table below. We invite public comment on these proposals.

Topic	17 Measures proposed for removal from hospital IQR program measure set for FY 2015 and subsequent payment determinations
Surgical Care Improvement Project (SCIP) Measures.	• SCIP INF VTE–1 Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered.
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures.	• PSI 06 Iatrogenic pneumothorax, adult. • PSI 11 Post Operative Respiratory Failure. • PSI 12 Post Operative PE or DVT. • PSI 14 Postoperative wound dehiscence. • PSI 15 Accidental puncture or laceration. • IQI 11 Abdominal aortic aneurysm (AAA) mortality rate (with or without volume). • IQI 19 Hip fracture mortality rate. • IQI 91 Mortality for selected medical conditions (composite).
Hospital Acquired Condition Measures.	• Foreign Object Retained After Surgery. • Air Embolism. • Blood Incompatibility. • Pressure Ulcer Stages III & IV. • Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock). • Vascular Catheter-Associated Infection. • Catheter-Associated Urinary Tract Infection (UTI). • Manifestations of Poor Glycemic Control.

d. Suspension of Data Collection for the FY 2014 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51611), we suspended data collection for four measures beginning with January 1, 2012 discharges, affecting the FY 2014 payment determination and subsequent years.

Topic	Hospital IQR program measures suspended for FY 2015 payment determination and subsequent years
Acute Myocardial Infarction (AMI) ..	• AMI–1 Aspirin at arrival. • AMI–3 ACEI/ARB for left ventricular systolic dysfunction. • AMI–5 Beta-blocker prescribed at discharge.
Surgical Care Improvement Project (SCIP).	• SCIP INF–6 Appropriate Hair Removal.

We suspended, rather than removed, these measures because although our analysis indicated that these measures are topped-out measures (that is, their performance is uniformly high nationwide, with little variability among hospitals), some commenters still believed that the processes assessed by the measures were tied to better patient outcomes, and that removal of the measures from the program may result in declines in performance and hence worse outcomes.

The suspension of data collection for these four measures will be continued unless we have evidence that performance on the measures is in danger of declining. Should we determine that hospital adherence to these practices has unacceptably declined, we would resume data collection using the same form and manner and on the same quarterly schedule that we finalize for these and other chart abstracted measures, providing at least 3 months of notice prior to resuming data collection. Hospitals would be notified of this via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before resuming data collection of these four measures.

3. Proposed Measures for the FY 2015 and FY 2016 Hospital IQR Program Payment Determinations

a. Additional Considerations in Expanding and Updating Quality Measures Under the Hospital IQR Program

In general, we seek to adopt measures for the Hospital IQR Program that would promote better, safer, more efficient care. We believe it is important to expand the pool of measures to include measures that aim toward improving patient safety. This goal is supported by many reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.[48,49]

In addition to our goals to align measures and support the Hospital VBP Program, we also take into account other considerations in implementing and expanding the Hospital IQR Program:

• Our overarching purpose is to support the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care. The Hospital IQR Program will help achieve the three-part aim by creating transparency around the quality of care at inpatient hospitals to support patient decision-making and quality improvement. Given the availability of well-validated measures and the need to balance breadth with minimizing burden, measures should take into account and address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy: Clinical care; Person- and caregiver-centered experience and outcomes; Safety; Efficiency and cost

[48] OEI–06–09–00090, ''Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries.'' Department of Health and Human Services, Office of Inspector General, November 2010.

[49] 2009 National Healthcare Quality Report, pp. 107–122. ''Patient Safety,'' Agency for Healthcare Research and Quality.

reduction; Care coordination; and Community/population health. More information regarding the National Quality Strategy can be found at: *http://www.hhs.gov/secretary/about/priorities/priorities.html* and *http://www.ahrq.gov/workingforquality/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.

• We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. Within the framework of our statutory authority and taking into account programmatic considerations, measures used in the Hospital IQR Program should be harmonized with other Medicare/Medicaid quality reporting programs and incentive programs to promote coordinated efforts to improve quality.

• As part of our burden reduction efforts, we will continuously weigh the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR Program. We seek to use measures based on alternative sources of data that do not require chart abstraction or that utilize data already being reported by many hospitals, such as data that hospitals report to clinical data registries, or all-payer claims databases. In recent years we have adopted measures that do not require chart abstraction, including structural measures and claims-based measures that we can calculate using other data sources.

• To the extent practicable, measures we use should be nationally endorsed by a multistakeholder organization. Section 3001(a)(2) of the Affordable Care Act added new sections 1886(b)(3)(B)(viii)(IX)(aa) and (bb) of the Act. These sections state that ''* * * effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a) [of the Act],'' and ''[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' Accordingly, we attempt to utilize endorsed measures whenever possible.

• Measures should be developed with the input of providers, purchasers/payers, and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

• Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multistakeholder groups in selecting quality and efficiency measures that have been endorsed by the entity with a contract under section 1890 of the Act, currently NQF, and measures that have not been endorsed. The MAP is a partnership comprised of multi-stakeholder groups that was convened by NQF to provide input on measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures (*http://www.qualityforum.org.map/*).

• HHS Strategic Plan and Initiatives. HHS is the U.S. government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The goals of the HHS Strategic Plan for Fiscal Years 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf*). HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries, and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce HAIs in clinical settings and the Partnership for Patients exemplify these programs.

• CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

• We give priority to measures that assess performance on: (a) Conditions that result in the greatest mortality and morbidity in the Medicare population; (b) conditions that are high volume and high cost for the Medicare program; and (c) conditions for which wide cost and treatment variations in the Medicare population have been reported, despite established clinical guidelines, across populations or geographic areas.

• We will focus on selecting measures that we believe will also meet the Hospital VBP Program measure inclusion criteria and advance the goals of the Hospital VBP Program by targeting hospitals' ability to improve patient care and patient outcomes.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50191 through 502192), we finalized our proposal to adopt measures for the Hospital IQR Program for three consecutive payment determinations. The intent of this policy was to provide greater certainty for hospitals to plan to meet future reporting requirements and implement related quality improvement efforts. In addition to giving hospitals more advance notice in planning quality reporting, this multiyear approach also provides more time for us to prepare, organize and implement the infrastructure needed to collect data on the measures and make payment determinations. However, we indicated that these finalized measure sets for multiple years could still be updated through the rulemaking process should we need to respond to agency and/or legislative changes.

Finally, in section IV.A.5.a.(2) of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219 through 50220), we adopted a proposal to make Hospital IQR Program payment determinations beginning with FY 2013 using one calendar year of data for chart-abstracted measures. We began using this approach, which synchronizes the quarters for which data on these measures must be submitted during each year with the quarters used to make payment determinations with respect to a fiscal year, beginning with January 1, 2011 discharges. However, it will not affect our payment determinations until FY 2013.

b. Proposed Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

(1) Process for Retention of Hospital IQR Program Measures Adopted in Previous Payment Determinations

We previously finalized 76 measures for the FY 2015 Hospital IQR Program measure set (76 FR 51636 through 51637). We note that this number includes the four measures for which we have suspended data collection.

In past rulemakings, we have proposed to retain previously adopted measures for each payment determination on a year-by-year basis and invited public comment on the proposal to retain such measures for all future payment determinations unless otherwise specified. Specifically, for the purpose of streamlining the rulemaking process, we are proposing that when we adopt measures for the Hospital IQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. We invite public comment on this approach.

(2) Proposed Additional Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636 through 51637), we finalized 17 new measures for the Hospital IQR measure set for FY 2015 payment determination: 3 HAI measures collected through the NHSN, (MRSA Bacteremia, C. difficile SIR, and the Healthcare Personnel Influenza Vaccination), the Stroke measure set (8 measures) and the VTE measure set (6 measures).

(A) Proposed New Survey-Based Measure Items for Inclusion in the HCAHPS Survey Measure for the FY 2015 Payment Determination and Subsequent Years

For the FY 2015 payment determination and subsequent years, we are proposing to add the NQF-endorsed 3-Item Care Transition Measure (CTM–3) (NQF #0228) to the existing HCAHPS survey. This measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The 3-Item Care Transition was developed by the University of Colorado Health Sciences Center for the NQF Endorsement Project entitled ''National Voluntary Consensus Standards for Quality of Cancer Care.'' The MAP supports the immediate inclusion of the CTM–3 measure within the Hospital IQR Program. The three care transitions items that comprise the CTM–3, which we are proposing to add to the HCAHPS survey beginning with January 2013 discharges, are listed below. Detailed information on scoring methodology can be found on the Care Transition Measure Web site: *http://www.caretransitions.org/documents/CTM3Specs0807.pdf.*

The HCAHPS Survey was designed to accommodate the addition of supplemental items, provided such items adhere to the relevant HCAHPS survey protocols, see HCAHPS Quality Assurance Guidelines V7.0, p. 72: *http://www.hcahpsonline.org/files/HCAHPS%20Quality%20Assurance%20Guidelines%20V7.0%20March%202012.pdf.* The survey items that comprise the CTM–3 that we propose to add to HCAHPS meet these protocols. The addition of select items to HCAHPS is consistent with the survey's original design, development and NQF endorsement. Further, the CTM–3 was designed by its developers to be consistent and compatible with extant HCAHPS items and HCAHPS sampling and survey administration protocols. The original, NQF-endorsed CTM–3 items and response options are as follows:

- The hospital staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left the hospital.
  - ☐ Strongly Disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly Agree
  - ☐ Don't Know/Don't Remember/Not Applicable
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
  - ☐ Strongly Disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly Agree
  - ☐ Don't Know/Don't Remember/Not Applicable
- When I left the hospital, I clearly understood the purpose for taking each of my medications.
  - ☐ Strongly Disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly Agree
  - ☐ Don't Know/Don't Remember/Not Applicable

In order to make the CTM–3 items more fully consistent and compatible with the original HCAHPS Survey items, we have made a few small modifications. Specifically, we are proposing: (1) To slightly reword the first care transition item by adding the phrase, ''During this hospital stay;'' (2) to delete the ''Don't Know/Don't Remember/Not Applicable'' response option from each item; and (3) to add a new response option, ''I was not given any medication when I left the hospital,'' to the third care transition item. These small modifications preserve the integrity and utility of the HCAHPS Survey as it is expanded to encompass a new dimension of patients' experience of hospital care. The developer of the CTM–3 has agreed to these modifications, which we believe are consistent with the NQF endorsements of the original 27-item HCAHPS Survey and of the CTM–3.

After incorporating these modifications, the CTM–3 items that we are proposing to add to the HCAHPS Survey are as follows:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I clearly understood the purpose for taking each of my medications.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
  - ☐ I was not given any medication when I left the hospital

We also are proposing to add two items to the ''About You'' section of the HCAHPS survey beginning with January 2013 discharges. These two items would not be included in public reporting of the HCAHPS survey but may be employed in the patient-mix adjustment of survey responses.

The two proposed ''About You'' items are as follows:

- During this hospital stay, were you admitted to this hospital through the Emergency Room?
  - ☐ Yes
  - ☐ No
- In general, how would you rate your overall mental or emotional health?
  - ☐ Excellent
  - ☐ Very good
  - ☐ Good
  - ☐ Fair
  - ☐ Poor

The two new ''About You'' items were developed and tested in the Three-State Pilot Study of HCAHPS in 2003. Neither item was adopted in the national implementation of HCAHPS in 2006; however, current circumstances, as explained below, warrant the addition of these items to the HCAHPS survey at this time. We invite public comment on the two proposed ''About You'' items.

Until 2010, ''emergency room admission'' as a point of origin for hospital patients was an administrative code provided by hospitals and was used as a patient-mix adjustment for HCAHPS scores. However, since July 2010, the ''Point of Origin for Admission or Visit'' code for Emergency Room has been discontinued for use by Medicare payment systems and, thus became unavailable for HCAHPS patient-mix adjustment. In the original HCAHPS mode experiment, we determined empirically that emergency room admission status both vary across hospitals and have an important bearing on patient experience of care: *http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf.* The inclusion of a new patient-reported survey item will allow us to again use emergency room admission as a patient-mix adjustment variable.

We have received numerous inquiries and requests from hospitals and researchers to add a survey item concerning the patient's overall mental health. The survey item we are proposing to add, which is very similar in structure to the existing ''overall health'' item, will allow us to introduce a patient-mix adjustment for this characteristic in the future. Although we chose not to add a survey item about patient's overall mental health status in the national implementation of HCAHPS in 2006, we continue to receive inquiries and requests from hospitals and researchers on this topic. Some researchers claim that mental health status is an important factor in how patients respond to HCAHPS survey items. The continuing interest in this topic, coupled with the direct impact of HCAHPS performance on hospital payments beginning in October 2012, led to the decision to add an overall mental health item to the HCAHPS survey. The overall mental health survey item we have chosen very closely resembles the Overall General Health item in the HCAHPS Survey, has been extensively tested, and is currently included in several other CAHPS surveys.

We are proposing to add these two ''About You'' items to the existing HCAHPS survey, with required collection beginning January 1, 2013. More detail regarding HCAHPS requirements is included in the Form, Manner and Timing section of this preamble for this program. We invite public comment on the proposed addition of these items for the FY 2015 payment determination.

(B) Proposed New Claims-Based Measures for the FY 2015 Payment Determination and Subsequent Years

(i) Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1550)

The THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. In 2003, there were 202,500 THAs and 402,100 TKAs performed,[50] and the number of procedures performed annually has increased steadily over the past decades. Annual hospital charges are projected to increase by 340 percent to $17.4 billion for THA and by 450 percent to $40.8 billion for TKA by 2015. Annual hospital charges are projected to increase by 340 percent to $17.4 billion for THA and by 450 percent to $40.8 billion for TKA by 2015.[51] The post-operation complications of these procedures are high considering these are selective procedures and usually the complications are devastating to patients. For example, rates for periprosthetic joint infection, a rare but devastating complication, have been reported at 2.3 percent for THA/TKA patients with rheumatoid arthritis,[52] and 1.6 percent in primary elective TKA patients after 1 and 2 years of follow up, respectively.[53] Two studies reported 90-day death rates following THA at 0.7 percent[54] and 2.7 percent.[55] Reported rates for pulmonary embolism following TKA range from 0.5 percent to 0.9 percent.[56,57,58,59] Reported rates for septicemia range from 0.1 percent, during the index admission[60] to 0.3 percent, 90 days following discharge for primary TKA.[61] Rates for bleeding and hematoma following TKA have been reported at 0.94 percent[62] to 1.7 percent.[63] In 2005, annual hospital charges totaled $3.95 billion and $7.42 billion for primary THA and TKA, respectively.[64] Combined, THA and TKA procedures account for the largest payments for procedures under Medicare.[65]

Both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, and the volume and cost associated with these procedures are very high. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

The Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure (NQF # 1550) is an outcome measure. We are proposing this measure for the Hospital IQR Program because outcome measures are priority areas for the Hospital IQR Program. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures and publicly report

[50] Kurtz S, Ong K, Lau E, Mowat F, Halpern M., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780–785.

[51] Kurtz SM, Ong KL, Schmier J, et al., Future clinical and economic impact of revision total hip and knee arthroplasty. J Bone Joint Surg Am. Oct 2007;89 Suppl 3:144–151.

[52] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713–1720.

[53] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.

[54] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[55] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[56] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[57] Mahomed NN, Barrett JA, Katz JN, *et al.* Rates and outcomes of primary and revision total hip replacement in the United States medicare population. *J Bone Joint Surg Am.* Jan 2003;85–A(1):27–32.

[58] Khatod M, Inacio M, Paxton EW, *et al.* Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[59] Solomon DH, Chibnik LB, Losina E, *et al.* Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536–1542.

[60] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[61] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[62] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[63] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1):95–100.

[64] Kurtz S, Ong K, Lau E, Mowat F, Halpern M., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780–785.

[65] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008;23(6 Suppl 1):133–138.

the hospital rates for consumer choice of care.

The proposed measure assesses complications occurring after THA and TKA surgery from the date of the index admission to 90 days post date of the index admission. The outcome is one or more of the following complications: acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. The data indicated that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals. The variation in complication rates suggest that there are important differences in the quality of care delivered across hospitals, and that there is room for quality improvement.

In 2010, we developed a hospital-level risk-standardized complication rate (RSCR) following elective primary THA and TKA surgery. NQF endorsed this THA and TKA complication measure in February 2012 (NQF #1550). In its Pre-Rulemaking Report for 2012, the MAP also recommended the inclusion of this measure in the Hospital IQR Program. We are proposing to adopt the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure for the Hospital IQR Program for the FY 2015 payment determination and subsequent years. This measure is NQF-endorsed (NQF #1550); therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure specifications can be found at: *http://www.qualityforum.org/Projects/Surgery_Maintenance.aspx#t=2&s=&p=.*

The proposed measure uses the same hierarchical logistic modeling (HLM) methodology that is specified for other NQF-endorsed CMS inpatient outcome measures previously adopted for this program, including AMI, HF, and PN readmission and mortality measures because this modeling has already been subjected to NQF review, and has been determined to appropriately account for the types of patients a hospital treats, the number of patients it treats, and the quality of care it provides. The HLM model estimates risk-standardized complications rates. Medicare Part A and Part B (FFS) claims are the data source we used to develop the measure and that we are proposing to use to calculate the measure if finalized. Index admission diagnoses and in-hospital comorbidities would be assessed using Medicare Part A claims. Additional comorbidities prior to the index admission would be assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment and post-discharge mortality status would be obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

The proposed Total Hip and Total Knee Arthroplasty Complication measure includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-Federal acute care hospitals for THA or TKA. The measure methodology identifies eligible index admissions, using the following ICD–9–CM procedure codes: 81.51 Total Hip Arthroplasty; and 81.54 Total Knee Arthroplasty in Medicare Part A inpatient claims data. The measure specifications will be updated yearly and will be specified using ICD–10.

In addition, the proposed measure includes patients who have had continuous enrollment in Medicare FFS for one year prior to the date of index admission to ensure full data availability for risk adjustment. We restrict the sample to admissions of patients enrolled in Medicare FFS coverage in the 12 months prior to and including the time of their index admission to a non-Federal acute care hospital because of the availability of complete administrative data for most Medicare FFS patients.

The proposed measure does not include beneficiaries enrolled in Medicare Managed Care (''Medicare Advantage'') plans because only partial administrative data are reported to CMS. We would not have complete data on these Medicare Advantage enrollees. Patients under age 65 (the qualifying age for Medicare coverage for those not considered disabled or with end-stage renal disease) or for whom we otherwise have incomplete information—for example, those enrolled in a Medicare Advantage plan during any part of the relevant time period— will also be excluded to ensure data comparability. Additionally, these restrictions on the data allow for an appropriately comprehensive risk-adjustment for patient case-mix and comorbidity that would not be possible without access to data available to this population.

The proposed measure excludes patients with hip fractures (patients with hip fractures have higher mortality, complication rates and the procedure (THA) is not elective); patients undergoing revision procedures (may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication and readmission rates); patients undergoing partial hip arthroplasty (primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions) ; patients undergoing resurfacing procedures (different type of procedure which is typically performed on younger, healthier patients); patients who are transferred to the index hospital (it is likely that the procedure is not elective); patients who leave the hospital against medical advice (it is likely that the procedure is not elective); patients with more than two THA/TKA procedure codes during the index hospitalization (unlikely that patients would receive more than two THA/TKA procedures in one hospitalization, and this pattern may reflect coding errors); and patients with multiple admissions for THA/TKA in the 12 months studies.

Consistent with the requirements in section 1886(b)(3)(B)(viii)(VIII) of the Act, the proposed measure is risk-adjusted. It takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the Hierarchical Condition Categories (CC), which are clinically relevant diagnostic groups of ICD–9–CM codes.[66] The CCs used in the risk adjustment model for this measure, are provided at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1182785083979*. The proposed measure meets the statutory requirement because it adjusted for hospital patient mix including age and comorbidities to ensure that hospitals that care for a less healthy patient population are not penalized unfairly. The measure methodology defines ''complications'' as Acute myocardial infarction; Pneumonia; Sepsis/septicemia; Pulmonary embolism; Surgical site bleeding; Death; Wound infection; Periprosthetic joint infection; and Mechanical complication within 30 to 90 days post the index date of admission, depending on the complication. The decision on the appropriate follow-up period was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days

[66] Pope G, Ellis R, Ash A, *et al.,* Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

post the date of index admission. We found that the rates for four other complications—death, surgical site bleeding, wound infection, and pulmonary embolism—are elevated for 30 days, and that AMI, pneumonia, and sepsis/septicemia level off 7 days post date of index admission. The following table presents the follow-up period for each complication.

COMPLICATION FOLLOW-UP PERIODS

Complication	Follow-up period (days)
Death	30
Mechanical complications	90
Periprosthetic joint infection (PJI)	90
Surgical site bleeding	30
Wound infection	30
Pulmonary embolism	30
AMI	7
Pneumonia	7
Sepsis/septicemia	7

We are proposing to calculate the hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate.

We invite public comment on the proposed inclusion of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty measure in the Hospital IQR Program for the FY 2015 payment determination and future years. (ii) Hip/Knee Readmission: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1551)

As previously stated, outcome measures such as complications and readmissions are the priority areas for the Hospital IQR Program. The THA and TKA are commonly performed procedures that improve quality of life. The complications are usually devastating to the patient and costly to the Medicare program. Furthermore we believe that there is an opportunity for quality improvement by hospitals to improve quality of life for the patient. The 2008 Medicare FFS claims data indicate that 30-day hospital-level risk-standardized readmission rates ranged from 3.06 percent to 50.94 percent among hospitals with a median rate of 6.06 percent. The mean risk-standardized readmission rate was 6.3 percent. This variation suggests there are important differences in the quality of care received across hospitals, and that there is room for improvement.

Given the high volume and high cost associated with these hip and knee procedures (relative to other elective procedures performed in the Medicare population), we believe that it is imperative to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures. A measure that addresses readmission rates following THA and TKA provides an opportunity to provide targets for efforts to improve the quality of care and reduce costs for patients undergoing these elective procedures. The measure also increases transparency for consumers and provides patients with information that could guide their choices. Finally, it has the potential to lower health care costs associated with readmissions. The development of risk-adjusted measures of patient readmission outcomes can provide a critical perspective on the provision of care, and support improvements in care for the Medicare patient population following THA/TKA hospitalization.

We are proposing to adopt the Hip/Knee Readmission: Hospital 30-Day All-Cause Readmission Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure for the Hospital IQR Program for the FY 2015 payment determination and subsequent years. This measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure specification for this measure can be found on the Web site at: *http://www.qualityforum.org/Projects/Surgery_Maintenance.aspx#t=2&s=&p=*. In its Pre-Rulemaking Report, the MAP recommended the inclusion of this measure in the Hospital IQR Program. The objective of this proposed measure is to assess readmission from any cause within 30 days of the initial total hip arthroplasty and total knee arthroplasty admissions for patients discharged from the hospital following elective primary THA and TKA.

The proposed measure uses the same HLM methodology that is specified for the NQF-endorsed AMI, HF, and PN 30-day risk-adjusted all-cause readmission measures in the Hospital IQR Program because it has already been subjected to NQF review and has been determined to appropriately account for the types of patients the hospital treats, the number of patients it treats, and the quality of care it provides. The HLM model estimates risk-standardized readmission rates. The data source we used to develop the measure and that we would use to calculate the measure if finalized is Medicare Part A (FFS) claims. Index admission diagnoses and in-hospital comorbidity data would be assessed using Medicare Part A claims. Additional comorbidities prior to the index admission would be assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status would be obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

The proposed measure includes admissions for patients who were Medicare FFS beneficiaries, aged 65 years or older, admitted to non-Federal acute care hospitals with an ICD–9–CM code for THA or TKA. Eligible index admissions would be identified using the following ICD–9–CM procedure codes: 81.51 (Total hip arthroplasty); and 81.54 (Total knee arthroplasty) in Medicare Part A inpatient claims data.

In addition, patients must have had continuous enrollment in Medicare FFS for one year prior to the date of index admission to ensure full data availability for risk adjustment. We restrict the included cases to admissions of patients enrolled in Medicare FFS coverage in the 12 months prior to and including the time of their index admission to a non-Federal acute care hospital because of the availability of complete administrative data for most Medicare FFS patients.

We are proposing not to include beneficiaries enrolled in Medicare Managed Care (''Medicare Advantage'') plans because only partial administrative data are reported to CMS. We would not have complete data on these Medicare Advantage enrollees. Patients under age 65 (the qualifying age for Medicare coverage for those not considered disabled or with end-stage renal disease) or for whom we otherwise have incomplete information—for example, those enrolled in a Medicare Managed Care plan during any part of the relevant time period—will also be excluded to ensure data comparability.

We are proposing to exclude patients with hip fractures (patients with hip fractures have higher mortality, complication and readmission rates and the procedure (THA) is generally not elective); patients undergoing revision procedures (may be performed at a disproportionately small number of hospitals and are associated with higher readmission rates); patients undergoing

partial hip arthroplasty (partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions); patients undergoing resurfacing procedures (resurfacing procedures are a different type of procedure which are typically performed on younger, healthier patients); patients who are transferred into the index hospital (it is likely that the procedure is not elective); patients who are admitted for the index procedure and subsequently transferred to another acute care facility (attribution of readmission to the index hospital would not be possible in these cases); patients who leave the hospital against medical advice (providers do not have the opportunity to provide the highest quality care for these patients); patients with more than two THA/TKA procedure codes during the index hospitalization (unlikely that patients would receive more than two THA/TKA procedures in one hospitalization and this may reflect a coding error); patients without at least 30-days post-discharge enrollment in Medicare FFS (the 30-day readmission outcome cannot be assessed for the standardized time period); and patients who die during the index admission (patients who die during the initial hospitalization are not eligible for readmission).

The proposed measure methodology does not count readmissions that are associated with a subsequent ''planned'' THA/TKA procedure within 30-days of discharge from index hospitalization. Some patients may elect to stage their orthopedic replacement procedures across hospitalizations (for example, a patient may have the left and right knees replaced within one or two weeks of each other, potentially across multiple hospitalizations). The planned readmissions are defined as a second admission with a procedure code for THA or TKA AND a primary discharge diagnosis of osteoarthritis, rheumatoid arthritis, osteonecrosis, or arthropathy (excluding septic arthropathy).

Consistent with the requirements in section 1886(b)(3)(B)(viii)(VIII) of the Act, the proposed measure is risk-adjusted. It takes into account patient age and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for readmission using diagnosis codes collected from all patient claims one year prior to patient index hospitalization for THA and TKA. The patient diagnosis codes are grouped using Hierarchical Condition Categories (CCs), which are clinically relevant diagnostic groups of ICD–9–CM codes.[67]

The CCs used in the risk adjustment model for this measure, are provided at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694*. Patient risk factors are used to determine how sick the patients are on admission (that is, patient comorbidities). The hospital measure rates are calculated taking into account how sick their patients are. In summary, age and comorbidities present at the time of admission would be adjusted for differences in hospital case mix (patient risk factors).

The proposed measure uses the HLM methodology for risk adjustment. As we do for all the other 30-day readmission measures adopted for the Hospital IQR Program, we would calculate (using the HLM) the hospital risk-standardized readmission rate by producing a ratio of the number of ''predicted'' readmissions (that is, the adjusted number of readmissions at a specific hospital) to the number of ''expected'' readmissions (that is, the number of readmissions if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw readmission rate.

While the hip and knee complications measure will inform quality improvement efforts targeted toward minimizing medical and surgical complications during surgery and in the recovery phase, the hip and knee readmission measure portrays a broader range of medical and surgical outcomes affected by in-hospital care and the transition to post-acute care. This measure was endorsed by the NQF (#1551) and recommended by the MAP for the Hospital IQR Program in its Pre-Rulemaking report for 2012.

We are proposing to include the Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure in the Hospital IQR Program for the FY 2015 payment determination and future years. We invite public comment on this proposal.

(iii) Hospital-Wide Readmission (Tentative NQF #1789)

During 2003 and 2004, over 2.3 million Medicare patients (almost one fifth of all Medicare beneficiaries) were rehospitalized within 30 days of discharge from an acute care hospital, and it was estimated that readmissions within 30 days of discharge cost Medicare more than $17 billion annually.[68] In its 2007 Report to the Congress, MedPAC estimated that in 2005, 17.6 percent of hospital patients were readmitted within 30 days of discharge.[69] MedPAC estimated that the average payment for a ''potentially preventable'' readmission was approximately $7,200. A 2006 Commonwealth Fund Report estimated that if national readmission rates were lowered to the levels achieved by the top performing regions, Medicare would save $1.9 billion annually.[70] We believe that reducing preventable readmissions will bring down healthcare costs.

Since 2009, we have publicly reported risk-standardized readmission rates (RSRRs) for three conditions: heart failure (HF), pneumonia (PN) and acute myocardial infarction (AMI) on *Hospital Compare (http://www.hospitalcompare.hhs.gov/),* as part of the efforts to improve quality of care and lower healthcare costs. However, these three conditions account for only a relatively small proportion of total hospital readmissions. High RSRRs and substantial variations in hospital RSRRs were found. The median 30-day RSRRs across hospitals is 19.9 percent for AMI (range from 15.3 percent to 26.8 percent); 24.8 percent for HF (range from 17.0 percent to 33.0 percent); and 18.4 percent for PN (range from 13.8 percent to 26.4 percent).[71]

A hospital's readmission rate is affected by complex and critical aspects of care such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the outpatient environment. While disease-specific measures of readmission are useful in identifying deficiencies in care for specific groups of patients, they account for only a small minority of total readmissions.[72] By contrast, a hospital-

[67] Pope G, Ellis R, Ash A, *et al.,* Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

[68] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. Apr 2 2009;360(14):1418–1428.

[69] Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Promoting Greater Efficiency in Medicare. 2007.

[70] The Commonwealth Fund, Why Not the Best? Results from a National Scorecard on U.S. Health System Performance. 2006: Harrisburg, PA.

[71] Bernheim S, Wang Y, Grady J, *et al.* Measures Maintenance Technical Report: Acute Myocardial Infarction. Heart Failure, and Pneumonia 30-day Risk Standardized Mortality Measures. 2011; Available at: *http://www.qualitynet.org/.*

[72] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. Apr 2 2009;360(14):1418–1428.

wide, all-condition readmission measure could portray a broader sense of the quality of care in hospitals. Consequently, hospital-wide, all-condition readmission measures can promote hospital quality improvement and better inform consumers about care quality.

Studies have estimated the rate of preventable readmissions to be as low as 12 percent and as high as 76 percent.[73,74] Some readmissions are unavoidable, for example, those that result from inevitable progression of disease or worsening of chronic conditions. However, readmissions may also result from poor quality of care or inadequate transitional care. Randomized controlled trials have shown that improvement in the following areas can directly reduce hospital readmission rates: Quality of care during the initial admission; improvement in communication with patients, their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Successful randomized trials have reduced 30-day readmission rates by 20–40 percent.[75,76,77,78,79,80,81] Evidence that hospitals have been able to reduce readmission rates through these quality-of-care initiatives illustrates the degree to which hospital best practices can affect readmission rates.

Our Quality Improvement Organizations (QIOs) began projects to improve care transitions during the 9th Statement of Work in fourteen communities by applying successful interventions learned from clinical trials, such as medication reconciliation, increased patient education, follow up after discharge, and post-discharge instructions for patients.[82] Important interventions to integrate care for populations and communities now continue among all 53 QIOs on a national scale in the QIO 10th Statement of Work which began August 2011.

Because many studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, we believe that it is appropriate to include an all-condition readmission rate as a quality measure in the Hospital IQR Program. Promoting quality improvements leading to successful transition of care for patients from acute care to outpatient setting, and reducing short term, preventable hospital-wide readmission rates are CMS's priority objectives.

To provide a broader assessment of the quality of care at hospitals, especially for hospitals with too few AMI/HF/PN readmissions to count separately, we have developed a Hospital-Wide Readmission (HWR) measure using 2008 Medicare FFS data. Detailed information and specifications for this measure can be found on the NQF Web site at: *http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&s=&p=7%7C6%7C5%7C4%7C.* The objective of the proposed HWR measure is to assess the hospital-level, risk-standardized rate of unplanned, all-cause readmissions after admissions for any eligible condition within 30 days of hospital discharge. The proposed measure comprises a single summary score, derived from the results of five different models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): Medicine, surgery/gynecology; cardiorespiratory; cardiovascular; and neurology.

We are proposing to use one year of data to calculate the measure rate for the HWR measure, which we believe is sufficient to calculate this measure in a statistically reliable manner. The reliability of a hospital's measure rate is related to its sample size. For its rate to be calculated reliably statistically, a hospital needs to have a sufficient number of patient cases to which the measure applies. Because the proposed HWR measure addresses over 90 percent of Medicare FFS hospitalizations for patients aged 65 and older, we believe one year of data would yield a sufficient number of cases to assess hospital performance in a statistically reliable manner. In contrast, for the condition-specific readmission measures for AMI, Heart Failure and Pneumonia, each of which address a smaller proportion of Medicare FFS Hospitalizations than the HWR measure, we must use three years of data for to have a enough patient cases to calculate the rates for these measures. We also believe that use of one year of data for the HWR measure is appropriate because it allows us to calculate up-to-date hospital performance for the most recent year, rather than calculating hospital performance over the course of three years, as we must do for the AMI, HF, and PN readmission measures. The proposed measure methodology is described in greater detail below.

The proposed measure uses 30 days following the index admission as the timeframe for assessing hospital performance because within this timeframe, readmissions are more likely attributable to care received during the index hospitalization and during the transition to the outpatient setting. For example, hospitals, in collaboration with their medical communities take actions to reduce readmission, such as ensuring patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communications among providers involved in management principles, and educating patients about symptoms to monitor, whom to contact with questions, and where and when to seek follow-up care. Furthermore our ''time-to-event curve'' analyses showed a readmission curve with rapid early accrual of readmissions with a stable and consistent readmission rate thereafter; the curve typically stabilized within 30-days of discharge. Finally, the proposed 30-day timeframe is consistent with the other publicly reported CMS readmission measures endorsed by the NQF.

The proposed HWR measure defines the outcome as ''all-cause'' unplanned readmissions. Unplanned readmissions

[73] Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Inter Med 2000;160(8):1074–81.

[74] Medicare Payment Advisory Commission (U.S.). Report to the Congress promoting greater efficiency in Medicare. Washington, DC: Medicare Payment Advisory Commission, 2007.

[75] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, *et al.* A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009;150(3):178–87.

[76] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc 2004;52(11):1817–25

[77] Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. J Am Geriatr Soc 2009;57(3):395–402.

[78] Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomised controlled trial. BMC Public Health 2007;7:68.

[79] Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, *et al.* Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009;4(4):211–218.

[80] Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Ann Intern Med 1994;120(12):999–1006.

[81] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, *et al.* Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. Jama 1999;281(7):613–20.

[82] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, *et al.* A reengineered hospital discharge program to decrease rehospitalization: A randomized trial. Ann Intern Med 2009;150(3):178–87.

are acute clinical events experienced by a patient that require urgent hospital admission. Higher than expected unplanned readmission rates suggest lower quality of care and are the focus of quality measurement as part of quality improvement efforts. Because planned readmissions are not a signal of quality of care, we chose to exclude planned readmissions from being considered as an outcome for this measure. The proposed measure includes hospitalizations of patient who was age 65 or older (at the time of admission) who were in Medicare Fee-for-Service (FFS) for 12 months prior to the index admission, and who remained in Medicare FFS for at least 30-days post-discharge. The measure excludes patients who died during the index admission; patients who were transferred to another acute care hospital; patients who were discharged against medical advice; and patients who died within the 30-day post-discharge period. The measure also excludes admissions for medical treatment of cancer; for primary psychiatric disease (patients admitted for psychiatric treatment are typically cared for in separate psychiatric or rehabilitation centers which are not comparable to acute care hospitals); or for physical rehabilitation and prosthetic services.

The proposed measure excludes patients undergoing medical treatment for their cancer as their primary procedure because we concluded that readmission may not be a good quality indicator for this cohort of patients compared to other cohorts. For example, the cancer cohort had more than twice the post-discharge mortality of any other cohort. It also has a planned readmission rate six times that of any other cohort—41 percent of readmissions in this cohort were considered planned. This indicates that readmission in this population is a different phenomenon than for other cohorts. Most importantly, this cohort's risk standardized readmission ratio (SRR) was poorly correlated with the composite hospital-wide SRR of all other cohorts. Statistically this implies that readmission for the cancer cohort is likely measuring an aspect of quality very different from that for other cohorts. Consequently, we elected to exclude this subset of cancer patients from the measure.

For this measure, a patient is considered to have been readmitted if they experience one or more inpatient admissions within the 30 days after being discharged from an initial inpatient admission, whether the patient was readmitted to the same hospital or another. The proposed measure identifies ''planned readmissions'' in claims data that will not count as readmissions in the measure using an algorithm that identifies readmissions that are likely to be planned as opposed to readmissions due to probable complications. The algorithm was based on two main principles:

- The ''planned'' readmissions are those in which one of a pre-specified list of procedures took place (we refer readers to the measure methodology documentation on the NQF Web site at: *http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&p=2√3√&s* for the list), or those for maintenance chemotherapy or rehabilitation. Maintenance chemotherapy and rehabilitation are common planned readmissions that are reliably distinguishable in the data even though they are not accompanied by procedures.
- Admissions for acute illness or for complications of care are likely not ''planned.'' Clinically, any procedure completed during an admission for an acute illness is not likely to have been planned, even if that procedure is usually planned in other non-acute cases.

Therefore, the proposed measure uses procedure codes and discharge diagnosis categories for each readmission to identify planned readmissions. Readmissions that occur for planned procedures (we refer readers to the measure methodology report on the NQF Web site at: *http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&p=2√3√&s* for the list) and which are not for acute diagnoses or complications of care (listed below) are identified as planned.

For example, some patients have their gallbladders removed after having been identified as having symptomatic gallstones. Usually this is a surgery that is planned in advance and scheduled. However, occasionally a patient becomes acutely ill or has sudden inflammation or infection that requires a gallbladder surgery that was not planned in advance. The measure uses the patients' principal discharge diagnosis to differentiate between patients coming in for gallbladder removal with chronic gallstones (biliary disease) and patients acutely ill with inflamed gallbladders (cholecystitis) who are having an unplanned gallbladder removal.

Therefore, the proposed HWR measure defines planned readmissions which are excluded from the measure as any readmission:

- In which any of these procedures set out in the table below are performed if the discharge condition category is not acute or a complication of care, as discussed below; or
- For maintenance chemotherapy.

All other readmissions are considered unplanned and are counted as readmissions in the measure.

The following is the list of planned procedures based on the full AHRQ Clinical Classification Software (CCS) procedure category list.

PROCEDURE CATEGORIES CONSIDERED PLANNED DEPENDING ON THE DISCHARGE CONDITION

	Description
45	Percutaneous transluminal coronary angioplasty (PTCA).
	Rehabilitation (condition CCS 254).
84	Cholecystectomy and common duct exploration.
157	Amputation of lower extremity.
44	Coronary artery bypass graft (CABG).
78	Colorectal resection.
51	Endarterectomy; vessel of head and neck.
113	Transurethral resection of prostate (TURP).
99	Other OR gastrointestinal therapeutic procedures.
48	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator.
	Maintenance Chemotherapy (condition CCS 45).
211	Therapeutic radiology for cancer treatment.
3	Laminectomy; excision intervertebral disc.
43	Heart valve procedures.
152	Arthroplasty knee.
158	Spinal fusion.
55	Peripheral vascular bypass.
52	Aortic resection; replacement or anastomosis.
36	Lobectomy or pneumonectomy.
153	Hip replacement; total and partial.
60	Embolectomy and endarterectomy of lower limbs.
85	Inguinal and femoral hernia repair.
104	Nephrectomy; partial or complete.
1	Incision and excision of CNS.
124	Hysterectomy; abdominal and vaginal.
167	Mastectomy.
10	Thyroidectomy; partial or complete.
114	Open prostatectomy.
74	Gastrectomy; partial and total.
119	Oophorectomy; unilateral and bilateral.
154	Arthroplasty other than hip or knee.
	Radical laryngectomy, revision of tracheostomy, scarification of pleura (ICD–9 codes 30.4, 31.74, 34.6).
166	Lumpectomy; quadrantectomy of breast.

PROCEDURE CATEGORIES CONSIDERED PLANNED DEPENDING ON THE DISCHARGE CONDITION—Continued

	Description
64	Bone marrow transplant.
105	Kidney transplant.
176	Other organ transplantation.

PROCEDURE CATEGORIES CONSIDERED PLANNED DEPENDING ON THE DISCHARGE CONDITION—Continued

	Description
	Electroshock therapy (ICD–9 codes 94.26, 94.27).

The algorithm is designed to identify admissions for acute illness or complication of care as ''unplanned'' readmissions. The acute and complication discharge condition categories for unplanned readmissions are listed below.

DISCHARGE CONDITION CATEGORIES CONSIDERED ACUTE OR COMPLICATIONS OF CARE

AHRQ CCS	Description
237	Complication of device; implant or graft.
106	Cardiac dysrhythmias.
	Fracture (condition CCS 207, 225, 226, 227, 229, 230, 231, 232).
100	Acute myocardial infarction.
238	Complications of surgical procedures or medical care.
108	Congestive heart failure; nonhypertensive.
2	Septicemia (except in labor).
146	Diverticulosis and diverticulitis.
105	Conduction disorders.
109	Acute cerebrovascular disease.
145	Intestinal obstruction without hernia.
233	Intracranial injury.
116	Aortic and peripheral arterial embolism or thrombosis.
122	Pneumonia (except that caused by TB or sexually transmitted disease).
131	Respiratory failure; insufficiency; arrest (adult).
157	Acute and unspecified renal failure.
201	Infective arthritis and osteomyelitis (except that caused by TB or sexually transmitted disease).
153	Gastrointestinal hemorrhage.
130	Pleurisy; pneumothorax; pulmonary collapse.
97	Peri-; endo-; and myocarditis; cardiomyopathy.
127	Chronic obstructive pulmonary disease and bronchiectasis.
55	Fluid and electrolyte disorders.
159	Urinary tract infections.
245	Syncope.
139	Gastroduodenal ulcer (except hemorrhage).
160	Calculus of urinary tract.
112	Transient cerebral ischemia.
	All condition categories.

To compare readmission performance across hospitals, the proposed measure accounts for differences in patient characteristics (patient case mix) as well as differences in mixes of services and procedures offered by hospitals (hospital service-mix). The proposed measure includes 93.4 percent of Medicare FFS hospitalizations occurring in 2008, and includes 92.1 percent of readmissions following those hospitalizations.

The proposed measure uses the conditions and procedures defined by the AHRQ CCS, which is a widely used and accepted method of grouping patients into diagnostic categories. The AHRQ CCS collapsed the more than 17,000 different ICD–9–CM diagnosis and procedure codes into 285 clinically-coherent, mutually-exclusive condition categories and 231 mutually-exclusive procedure categories. We created five major specialty cohorts based on organization of care (medical, surgery/gynecology, cardiorespiratory, cardiovascular, and neurology), and assigned each condition category to a cohort. Admissions that included major surgical procedures (regardless of condition category) were assigned to the surgery/gynecology cohort. We estimated separate adjustment coefficients for each cohort using a single set of risk factors. We used hierarchical logistic regression to adjust for differences in hospital case mix and to account for the clustering of patients within a hospital. We adjusted for case mix differences among hospitals by risk-adjusting for patients' comorbid conditions identified in inpatient episodes of care for the 12 months prior to the index admission as well as those present at admission. We did not risk adjust for diagnoses that may have been a complication of care during the index admission. We used CMS Condition Category groups (CMS–CCs) to define the comorbid risk adjusters and used a fixed set of comorbid risk variables across models. We risk adjusted for service mix differences among hospitals within each major cohort by including indicator variables for discharge condition categories (as defined by AHRQ CCS) in each model.

Finally, we used each of the five cohort models to calculate predicted and expected numbers of readmissions for each hospital in each cohort. We then derived a single summary score from the results of the five models by calculating the volume-weighted log average of the predicted over expected ratios from each model and multiplying the resulting ratio by the average national readmission rate. This approach allowed us to take into account the variation in hospital specialty cohort mix.

The proposed HWR measure was recommended to the NQF board of directors for endorsement in March 2012 by the NQF Consensus Standards Approval Committee (CSAC). The MAP supported selection of the HWR measure for the Hospital IQR Program contingent on NQF endorsement. This measure is in the final stages of the NQF measure endorsement process, and we

expect its endorsement to be finalized in the coming months.

We are proposing to adopt this measure in the Hospital IQR Program for the FY 2015 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed the NQF-endorsed measures, and we were unable to identify any other NQF-endorsed measures that assess hospital-wide readmissions. We also are not aware of any other hospital-wide readmission measures that have been endorsed or adopted by a consensus organization other than NQF. The one other hospital-wide readmissions measure of which we are aware is the Risk-Adjusted 30-Day All-Cause Readmission Rate measure (formerly NQF #0329). This measure was endorsed by NQF, but NQF removed the measure's endorsement during a recent consensus development project that recommended endorsement of the HWR measure. Accordingly, we propose to adopt the HWR measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act. We invite public comment on this proposal.

(C) Proposed New Chart-Abstracted Measure: Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (NQF #0469)

For the FY 2015 payment determination and subsequent years, we are proposing to add a chart-abstracted measure, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. In launching the Strong Start Initiative (*http://www.innovation.cms.gov/initiatives/strong-start/*) to help reduce preterm births, the HHS Secretary indicated in a press release that more than half a million infants are born prematurely in America each year, and that this trend has increased 36 percent over the last 20 years. Preterm births may require additional medical attention and early intervention services. Some recent research indicates that elective deliveries before 39 weeks increase the risk of significant complications for mother and baby, as well as long-term health problems.[83,84,85,86] Preterm births are a growing public health problem that has significant consequences for families well into a child's life.

As a public campaign to reduce preterm births, the Strong Start Initiative's objective is to test ways to reverse this trend by helping provide expectant mothers with the care they need for a healthy delivery and a healthy baby, and by focusing on reducing early elective deliveries, which can lead to a variety of health problems for mothers and infants.

The Strong Start Initiative cuts across many agencies within HHS and involves external organizations including the March of Dimes, and the American College of Obstetricians and Gynecologists (ACOG). We believe that a reduction in the number of nonmedically indicated elective deliveries at >=37 to <39 weeks gestation will result in a substantial decrease in neonatal morbidity and mortality, as well as a significant savings in healthcare costs. In addition, the rate of cesarean sections should decrease with fewer elective inductions resulting in decreased length of stay and healthcare costs. The proposed measure would assist hospitals in tracking nonmedically indicated early term elective deliveries and reduce the occurrence of such deliveries. This measure would assess patients with elective vaginal deliveries or elective cesarean sections at >=37 and <39 weeks of gestation completed. The numerator for this measure is the number of patients with elective deliveries with principal or other procedure codes for one or more of the following: Medical induction of labor, and cesarean section while not in active labor or experiencing spontaneous rupture of membranes. Exclusions are: Less than 8 years of age; Greater than or equal to 65 years of age; Length of Stay >120 days; and enrolled in clinical trials.

We are proposing to adopt this measure for the Hospital IQR Program because we believe this measure furthers the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and low costs for health care. Additionally, we have determined that the measure is relevant to the nearly 2 million Medicare beneficiaries who are aged 44 and under, most of whom are dual eligible beneficiaries, who have the potential to be impacted by pre-term births. This is evidenced by the fact that, in 2011, Medicare paid for roughly 14,000 births. The measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure is currently under NQF maintenance review. In its Pre-Rulemaking report for 2012, the MAP also recommended the inclusion of this measure in the Hospital IQR Program. TJC is the measure steward of this measure and the detailed measure specification can be found on the TJC Web site at: *http://manual.jointcommission.org/releases/TJC2012A/MIF0166.html*.

We are proposing to add this measure to the Hospital IQR Program for the FY 2015 payment determination, with collection beginning with January 1, 2013 discharges. Although this measure is chart-abstracted, we are proposing that this measure would be collected in aggregated numerator, denominator, and exclusion counts per hospital via a Web-based tool (as opposed to collecting patient-level data from hospitals). Specific details regarding this proposed approach to data collection are included in section VIII.A.5. of this preamble on the form, manner, and timing of quality data submission for the Hospital IQR Program. We anticipate that the e-specifications of this measure will be completed in the summer of 2012. We intend to move to EHR-based collection of this and other measures once the necessary infrastructure to do so is in place. We invite public comment on our proposal to adopt this measure.

(D) Clarification Regarding Existing Hospital IQR Program Measures That Have Undergone Changes During NQF Measure Maintenance Processes

As discussed previously, once adopted, we retain measures in the Hospital IQR Program unless specifically stated otherwise. Recently the CLABSI and CAUTI measures were expanded to pertain to non-ICU locations in hospitals and to other types of care settings as part of NQF

[83] Glantz, J. (Apr. 2005). Elective induction vs. spontaneous labor associations and outcomes. *J Reprod Med*. 50(4):235–40.

[84] Vardo, J., Thornburg, L., Glantz, J., (2011). Maternal and neonatal morbidity among nulliparous women undergoing elective induction of labor. J. Reprod Med. 56(1–2): 25–30.

[85] Tita, A., Landon, M., Spong, C., Lai, Y., Leveno, K., Varner, M, *et al*. (2009). Timing of elective repeat cesarean delivery at term and neonatal outcomes. [Electronic Version]. *NEJM*. 360:2, 111–120.

[86] Clark, S., Miller, D., Belfort, M., Dildy, G., Frye, D., & Meyers, J. (2009). Neonatal and maternal outcomes associated with elective delivery. [Electronic Version]. *Am J Obstet Gynecol*. 200:156.e1–156.e4.

maintenance review. These measures retained their original NQF numbers as these changes were not considered substantive. However, we will continue to require hospitals to submit data for these two measures on ICU locations only for the Hospital IQR Program. We seek comment from hospitals on the feasibility and timing of expanding collection of these measures to include non-ICU locations in hospitals.

NQF, in addition to expanding the care settings to which the CLABSI and CAUTI measures could apply, also changed how these measures are calculated. The original endorsed version of the measures calculated an infection rate per 1,000 central line days for CLABSI and for 1,000 urinary catheter days for CAUTI. In the course of its maintenance review, NQF changed the way the measures are calculated from an infection rate per 1,000 days to a standardized infection ratio (''SIR''), which is comprised of the actual rate of infection over the expected rate of infection. We note that although the previously endorsed versions of the CAUTI and CLABSI measures did not include the SIR calculation, we have reported the CDC-calculated SIR for both measures on the *Hospital Compare* Web site. While use of this calculation is different from the original NQF-endorsed measure output, we believe the SIR is a more accurate way to calculate the CLABSI and CAUTI measures for comparative purposes rather than the rate per 1,000 infection days because it takes into account hospitals' case mix. We will continue to report SIRs for both measures because this calculation is now consistent with NQF's endorsement of the measures. We also note that use of the SIR calculation does not change the type of data that hospitals submit on the CLABSI and CAUTI measures.

In summary, we are proposing the removal of 17 measures (1 chart-abstracted measure and 16 claims-based measures) from the measure set for the FY 2015 payment determination and subsequent years. We are proposing to add survey items to the existing HCAHPS survey. We also are proposing to add 3 claims-based measures and 1 chart-abstracted measure to the measure set for the FY 2015 payment determination and subsequent years, for a total of 59 measures. These 59 measures are listed below.

Topic	Proposed hospital IQR program measures for FY 2015 payment determination and subsequent years
Acute Myocardial Infarction (AMI) Measures.	• AMI–2 Aspirin prescribed at discharge. • AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival. • AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI). • AMI–10 Statin Prescribed at Discharge.
Heart Failure (HF) Measures	• HF–1 Discharge instructions. • HF–2 Evaluation of left ventricular systolic function. • HF–3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction.
Stroke (STK) Measure Set	• STK–1 VTE prophylaxis. • STK–2 Antithrombotic therapy for ischemic stroke. • STK–3 Anticoagulation therapy for Afib/flutter. • STK–4 Thrombolytic therapy for acute ischemic stroke. • STK–5 Antithrombotic therapy by the end of hospital day 2. • STK–6 Discharged on Statin. • STK–8 Stroke education. • STK–10 Assessed for rehab.
VTE Measure Set	• VTE–1 VTE prophylaxis. • VTE–2 ICU VTE prophylaxis. • VTE–3 VTE patients with anticoagulation overlap therapy. • VTE–4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol. • VTE–5 VTE discharge instructions. • VTE–6 Incidence of potentially preventable VTE.
Pneumonia (PN) Measures	• PN–3b Blood culture performed in the emergency department prior to first antibiotic received in hospital. • PN–6 Appropriate initial antibiotic selection.
Surgical Care Improvement Project (SCIP) Measures.	• SCIP INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision. • SCIP INF–2 Prophylactic antibiotic selection for surgical patients. • SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery). • SCIP INF–4 Cardiac surgery patients with controlled 6AM postoperative serum glucose. • SCIP INF–9 Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero. • SCIP INF–10 Surgery patients with perioperative temperature management. • SCIP Cardiovascular–2 Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period. • SCIP–VTE–2 Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery.
Mortality Measures (Medicare Patients).	• Acute Myocardial Infarction (AMI) 30-day mortality rate. • Heart Failure (HF) 30-day mortality rate. • Pneumonia (PN) 30-day mortality rate.
Patients' Experience of Care Measures.	• HCAHPS survey (expanded to include one 3-item care transition set* and two new ''About You'' items).
Readmission Measures (Medicare Patients).	• Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure. • Heart Failure 30-day Risk Standardized Readmission Measure. • Pneumonia 30-day Risk Standardized Readmission Measure. • 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty.* • Hospital-Wide All-Cause Unplanned Readmission (HWR).*
AHRQ Patient Safety Indicators (PSIs) Composite Measures.	• Complication/patient safety for selected indicators (composite).

Topic	Proposed hospital IQR program measures for FY 2015 payment determination and subsequent years
AHRQ PSI and Nursing Sensitive Care.	• PSI–4 Death among surgical inpatients with serious treatable complications.
Structural Measures	• Participation in a Systematic Database for Cardiac Surgery. • Participation in a Systematic Clinical Database Registry for Stroke Care. • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. • Participation in a Systematic Clinical Database Registry for General Surgery.
Healthcare-Associated Infections Measures.	• Central Line Associated Bloodstream Infection. • Surgical Site Infection. • Catheter-Associated Urinary Tract Infection. • MRSA Bacteremia. • Clostridium Difficile (C.Diff). • Healthcare Personnel Influenza Vaccination.
Surgical Complications	• Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty.*
Emergency Department (ED) Throughput Measures.	• ED–1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital. • ED–2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status.
Prevention: Global Immunization (IMM) Measures.	• Immunization for Influenza. • Immunization for Pneumonia.
Cost Efficiency	• Medicare Spending per Beneficiary.
Perinatal Care	• Elective delivery prior to 39 completed weeks of gestation.*

* New measures/items proposed for the FY 2015 payment determination and subsequent years.

c. Proposed Hospital IQR Program Quality Measures for the FY 2016 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74466), we adopted the Safe Surgery Checklist Use measure for the Hospital OQR Program for CY 2014 payment determination. In the same rule, we adopted this measure for the ASCQR Program for CY 2015 payment determination (76 FR 74507). This structural measure assesses whether a hospital outpatient department utilizes a Safe Surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods: (1) The period prior to the administration of anesthesia; (2) the period prior to skin incision; and (3) the period of closure of incision and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications, and post-surgical mortality.[87] Like hospital outpatient settings and ambulatory surgical centers, acute care hospitals also perform many surgical procedures. Therefore, we believe this measure is also applicable for hospital inpatient settings in strengthening patient safety precautions in hospitals and we are proposing to adopt this measure for the Hospital IQR Program for FY 2016 payment determination and subsequent years.

For this proposed structural measure, a hospital inpatient department would indicate whether or not it uses a safe surgery checklist for its surgical procedures that includes safe surgery practices during each of the three critical perioperative periods discussed above. The measure would not require a hospital to report whether it uses a checklist in connection with any individual inpatient procedures. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74505 through 74506) for the detailed discussion of the Safe Surgery Checklist Use measure.

We are proposing to adopt this Safe Surgery Checklist structural measure, which is not NQF-endorsed, under the exception authority provided in section 1886(b)(3)(B)(IX)(bb) of the Act. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed the NQF-endorsed measures, and we were unable to identify any NQF-endorsed measures that assess use of safe surgery checklists. We also are not aware of any other safe surgery checklist use measures that have been endorsed or adopted by a consensus organization other than NQF. Accordingly, we propose to adopt the Safe Surgery Checklist measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act.

This measure was included on the pre-rulemaking list for consideration by the MAP, and this multistakeholder organization comprised of affected parties supported the direction of this measure pending availability of specifications. These specifications will be made available in an upcoming manual release for the ASC Quality Reporting Program which will be available on Quality Net Web site at *http://www.qualitynet.gov*. The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety, which is comprised of the American Association of Nurse Anesthetists, the American College of Surgeons, the American Association of Surgical Physician Assistants, the American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, the AORN, and the Association of Surgical Technologists. Two State agencies (Oregon and South Carolina), the Veterans Health Administration,[88] numerous hospital systems, State hospital associations (such as California

[87] Haynes, A.B.; Weiser, T.G.; Berry, W.G. *et al.* (2009). ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.'' New England Journal of Medicine. 360: 491–499.

[88] Neily, J; Mills, PD, Young-Xu, Y. (2010). ''Association between implementation of a Medical Team Training Program and Surgical Mortality.'' JAMA. 304 (15): 1693–1700.

and South Carolina), national accrediting organizations, and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[89,90] Although there is not currently an NQF endorsed measure for safe surgery checklist use, because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist use reflects consensus among affected parties. We also note that TJC included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals (NPSGs) adopted for 2011 for surgeries performed in ambulatory settings and hospitals.

Given that this measure is pivotal in preventing human errors in surgical operations which are commonly performed by acute care hospitals, we are proposing to adopt this measure for the Hospital IQR Program for the FY 2016 payment determination and subsequent years. This proposal would achieve our goal to align measures across settings.

In summary, we are proposing to add one new structural measure to the Hospital IQR measure set for the FY 2016 payment determination. The 60 measures for the FY 2016 payment determination and subsequent years are listed below.

Topic	Proposed hospital IQR program measures for FY 2016 payment determination and subsequent years
Acute Myocardial Infarction (AMI) Measures.	• AMI–2 Aspirin prescribed at discharge. • AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival. • AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI). • AMI–10 Statin Prescribed at Discharge.
Heart Failure (HF) Measures	• HF–1 Discharge instructions. • HF–2 Evaluation of left ventricular systolic function. • HF–3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction.
Stroke Measure (STK) Set	• STK–1 VTE prophylaxis. • STK–2 Antithrombotic therapy for ischemic stroke. • STK–3 Anticoagulation therapy for Afib/flutter. • STK–4 Thrombolytic therapy for acute ischemic stroke. • STK–5 Antithrombotic therapy by the end of hospital day 2. • STK–6 Discharged on Statin. • STK–8 Stroke education. • STK–10 Assessed for rehab.
VTE Measure Set	• VTE–1 VTE prophylaxis. • VTE–2 ICU VTE prophylaxis. • VTE–3 VTE patients with anticoagulation overlap therapy. • VTE–4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol. • VTE–5 VTE discharge instructions. • VTE–6 Incidence of potentially preventable VTE.
Pneumonia (PN) Measures	• PN–3b Blood culture performed in the emergency department prior to first antibiotic received in hospital. • PN–6 Appropriate initial antibiotic selection.
Surgical Care Improvement Project (SCIP) Measures.	• SCIP INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision. • SCIP INF–2 Prophylactic antibiotic selection for surgical patients. • SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery). • SCIP INF–4 Cardiac surgery patients with controlled 6AM postoperative serum glucose. • SCIP INF–9 Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero. • SCIP INF–10 Surgery patients with perioperative temperature management. • SCIP Cardiovascular–2 Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period. • SCIP–VTE–2 Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery.
Mortality Measures (Medicare Patients).	• Acute Myocardial Infarction (AMI) 30-day mortality rate. • Heart Failure (HF) 30-day mortality rate. • Pneumonia (PN) 30-day mortality rate.
Patients' Experience of Care Measures.	• HCAHPS survey (expanded to include one 3-item care transition set * and two new ''About You'' items).
Readmission Measures (Medicare Patients).	• Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure. • Heart Failure 30-day Risk Standardized Readmission Measure. • Pneumonia 30-day Risk Standardized Readmission Measure. • 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty.* • Hospital-Wide All-Cause Unplanned Readmission (HWR).*
AHRQ Patient Safety Indicators (PSIs) Composite Measures.	• Complication/patient safety for selected indicators (composite).
AHRQ PSI and Nursing Sensitive Care.	• PSI–4 Death among surgical inpatients with serious treatable complications.
Structural Measures	• Participation in a Systematic Database for Cardiac Surgery. • Participation in a Systematic Clinical Database Registry for Stroke Care. • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. • Participation in a Systematic Clinical Database Registry for General Surgery.

[89] Haynes, AB; Weiser, TG; Berry, WR *et al.* (2009) ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.'' NEJM. 360: 491–499.

[90] Birkmeyer, JD (2010) ''Strategies for Improving Surgical Quality—Checklists and Beyond.'' NEJM. 363: 1963–1965.

Topic	Proposed hospital IQR program measures for FY 2016 payment determination and subsequent years
Healthcare-Associated Infections Measures.	• Safe Surgery Checklist Use.** • Central Line Associated Bloodstream Infection. • Surgical Site Infection. • Catheter-Associated Urinary Tract Infection. • MRSA Bacteremia. • Clostridium Difficile (C.Diff). • Healthcare Personnel Influenza Vaccination.
Surgical Complications	• Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty.*
Emergency Department (ED) Throughput Measures.	• ED–1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital. • ED–2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status.
Prevention: Global Immunization (IMM) Measures.	• Immunization for Influenza. • Immunization for Pneumonia.
Cost Efficiency	• Medicare Spending per Beneficiary.
Perinatal Care	• Elective delivery prior to 39 completed weeks of gestation.*

* New measures/items proposed for FY 2015 payment determination and subsequent years.
** New measures proposed for FY 2016 payment determination and subsequent years.

4. Possible New Quality Measures and Measure Topics for Future Years

We anticipate that, as EHR technology evolves and more infrastructure is put in place, we will have the capacity to accept electronic reporting of many of the clinical chart-abstracted measures that are currently part of the Hospital IQR Program or have been proposed for adoption into the program. We intend for this future progress to significantly reduce the administrative burden on hospitals under the Hospital IQR Program. We recognize that considerable work needs to be done by measure owners and developers to make this possible with respect to the clinical quality measures that we proposed. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, and implementing such specifications into EHR technology to capture and calculate the results, and implementing the systems. We believe that at a future date, such as 2015, CMS and hospitals will be able to use EHR-based reporting for many chart-abstracted measures for the Hospital IQR Program, and we intend to work diligently toward this goal. We believe this will simplify measure collection and submission for the Hospital IQR Program, and will reduce the burden on hospitals to report chart-abstracted measures.

Once the e-specifications and the EHR-based collection mechanism are available for the smoking and alcohol cessations measures developed by TJC, we intend to propose two TJC smoking and alcohol cessation measure sets for inclusion in the Hospital IQR Program. Each of these TJC sets consists of four measures:

• Smoking Cessation Set—(1) TAM–1 Tobacco Use Screening; (2) TAM–2 Tobacco Use Treatment Provided or Offered; (3) TAM–3 Tobacco Use Treatment Management at Discharge; and (4) TAM–4 Assessing Status after Discharge, and

• Alcohol Cessation Set—(1) TAM–5 Alcohol Use Screening; (2) TAM–6 Alcohol Use Brief Intervention Provided or Offered; (3) TAM–7 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge; and (4) TAM–8 Substance Use: Assessing Status after Discharge.

These measure sets were recommended by the MAP for inclusion in the Hospital IQR Program, provided they complete the NQF endorsement process prior to inclusion. We invite public comment on our intention to propose these measure sets.

We also note that consistent with the updated NQF endorsements of the CLABSI (NQF #139) and CAUTI (NQF #138) measures, we intend to propose to collect data for non-ICU patients as well for these two measures at a future time, and we seek public comment on the feasibility and timing of expanding data collection for acute care hospitals.

We intend to support the following measure domains in the Hospital IQR measure set in future measurement proposals for the Hospital IQR Program: Clinical quality (for example, the AMI, HF, PN, STK, and VTE measures), care coordination (for example, the mortality measures), patient safety (for example, the SCIP and HAI measures), patient and caregiver experience of care (for example, the HCAHPS measure), population/community health (for example, the global immunization measures), and efficiency (for example, the Medicare Spending per Beneficiary measure). This approach will enhance better patient care while bringing the Hospital IQR Program in line with our other established quality reporting and pay-for-performance programs.

5. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (II) of the Act state that the applicable percentage increase, for FY 2007 and each subsequent fiscal year, shall be reduced by 2.0 percentage points (or, beginning with FY 2015, by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act)) for any subsection (d) hospital that does not submit quality data in a form and manner, and at a time, specified by the Secretary. CMS requires that hospitals submit data in accordance with the specifications for the appropriate discharge periods. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. Hospitals submit quality data through the secure portion of the QualityNet (formerly known as QualityNet Exchange) Web site (*https://www.QualityNet.org*). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements. Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements.

b. Proposed Procedural Requirements for the FY 2015 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are now codified in

regulation at 42 CFR 412.140. Hospitals should refer to the regulation for participation requirements. For the FY 2015 payment determination and future years, we are proposing to modify the following procedural requirements and the corresponding regulation text.

• In order to ensure that hospitals that participate in the Hospital IQR Program are submitting data for a full year, we are proposing that hospitals that would like to participate in the Hospital IQR Program for the first time, or that previously withdrew from the program and would like to participate again, must submit to CMS a completed Notice of Participation by December 31 of the calendar year preceding the first quarter of the calendar year in which the chart-abstracted IQR data submission is required for any given fiscal year. For example, if a hospital wishes to participate in FY 2015, it must submit a pledge by December 31, 2012, and submit data beginning with January 1, 2013 discharges. We also are proposing to modify our regulations at § 412.140(a)(3)(i) to reflect this proposed requirement.

• Currently, CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made. In order to decrease the time between final submission of IQR data and IQR payment determination notification for the hospitals, we are proposing that a subsection (d) hospital may withdraw from the Hospital IQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital must submit the withdrawal form by May 15 prior to the start of the payment year affected. For example, if a hospital seeks to withdraw from the FY 2015 payment determination, the hospital must submit the withdrawal form to CMS by May 15, 2014. If a hospital withdraws from the program, it will receive a reduction until such time as it meets the participation requirements. This proposal will also align with the final abstraction data submission deadline which will eliminate the burden of one extra deadline for providers and vendors. We also are proposing to modify our regulations at § 412.140(b) to reflect this proposed requirement.

c. Proposed Data Submission Requirements for Chart-Abstracted Measures

For FY 2015 andsubsequent years, we are proposing to retain the 4½ months quarterly submission deadline for chart-abstracted quality measures. We also are proposing to retain the aggregate population and sampling deadline of 4 months. Hospitals would continue to be required to submit aggregate population and sample size counts to CMS on a quarterly basis for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (76 FR 51640 through 51641). We are proposing the same 14-day period after the aggregate population and sample size count deadline to submit the required patient-level records. For the FY 2015 payment determination and subsequent years, hospitals must submit data for four consecutive calendar year discharge quarters. For example for FY 2015, the submission quarters are as follows: 1Q CY 2013, 2Q CY 2013, 3Q CY 2013 and 4Q CY 2013.

We are proposing to collect a new chart-abstracted measure for FY 2015, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. Although this is a chart-abstracted measure, we are proposing that this measure would be collected in aggregated numerator, denominator, and exclusion counts per hospital via a Web-based tool. The complete data submission requirements, submission deadlines, and data submission mechanism, known as the Web-Based Measure Tool, will be posted on the QualityNet Web site at: *http://www.qualitynet.org/*. The Web-Based Measure Tool will be an Internet database for hospitals to submit their aggregate data. We are proposing that hospitals submit data in accordance with the specifications for the appropriate proposed reporting periods to the Web-Based Measures Tool that will be found in the hospital section on the QualityNet Web site (*http://www.qualitynet.org/*).

d. Proposed Sampling and Case Thresholds Beginning With the FY 2015 Payment Determination

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), we continued, for the FY 2015 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) regarding hospital submission of population and sampling data. We are not proposing any changes to these requirements.

We strongly recommend that hospitals review the QIO Clinical Warehouse Feedback Reports and the Hospital IQR Program Provider Participation Reports that are available after patient-level data are submitted to the QIO Clinical Warehouse. We generally update these reports on a daily basis to provide accurate information to hospitals about their submissions. These reports enable hospitals to ensure that their data were submitted on time and accepted into the QIO Clinical Warehouse.

e. Proposed HCAHPS Requirements for the FY 2014, FY 2015, and FY 2016 Payment Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), beginning with discharges occurring in third quarter CY 2011, we established that hospitals will have about 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse.

Other than this change, we did not make any other changes to the HCAHPS requirements for the FY 2013 and FY 2014 Hospital IQR Program payment determinations, which were adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220).

For the FY 2016 Hospital IQR payment determinations, we are proposing to continue these HCAHPS requirements. Under these requirements, a hospital must continuously collect and submit HCAHPS data in accordance with the current HCAHPS *Quality Assurance Guidelines* and the quarterly data submission deadlines, both of which are posted at *http://www.hcahpsonline.org*. In order for a hospital to participate in the collection of HCAHPS data, a hospital must either: (1) Contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the hospital's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a survey vendor provided that the hospital attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at: *http://www.hcahpsonline.org*. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site. For the FY 2016 Hospital IQR Program, we are proposing that the HCAHPS data would be based on discharges from January 1, 2014 through December 31, 2014.

Every hospital choosing to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS survey administration.)

Hospitals are strongly encouraged to submit their entire patient discharge list, excluding patients who had requested ''no publicity'' status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We emphasize that hospitals must also provide the administrative data that is required for HCAHPS in a timely manner to their survey vendor. This includes the patient MS–DRG at discharge, or alternative information that can be used to determine the patient's service line, in accordance with the survey protocols in the most recent HCAHPS *Quality Assurance Guidelines.*

We note that the HCAHPS *Quality Assurance Guidelines* require that hospitals maintain complete discharge lists that indicate which patients were eligible for the HCAHPS survey, which patients were not eligible, and which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the *Quality Assurance Guidelines* located at *http://www.hcahpsonline.org* for details about HCAHPS eligibility and sample frame creation.) In addition, the hospital must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the hospital's behalf.

Hospitals must obtain and submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the hospital is too small to obtain 300 completed surveys. We wish to emphasize that the absence of a sufficient number of HCAHPS eligible discharges is the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. If a hospital obtains fewer than 100 completed surveys, the hospital's HCAHPS scores will be accompanied by an appropriate footnote on the *Hospital Compare* Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess hospital performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that hospitals employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) and the HCAHPS Review and Correction Report that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time, the data has been accepted into the QIO Clinical Warehouse, and the data accepted into the QIO Clinical Warehouse are complete and accurate.

In order to ensure compliance with HCAHPS survey and administration protocols, hospitals and survey vendors must participate in all oversight activities. As part of the oversight process, during the onsite visits or conference calls, the HCAHPS Project Team will review the hospital's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS *Quality Assurance Guidelines.* All materials relevant to survey administration will be subject to review. The systems and program review includes, but is not limited to: (a) Survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We point out that the HCAHPS *Quality Assurance Guidelines* state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS survey. If we determine that a hospital is not compliant with HCAHPS program requirements, we may determine that the hospital is not submitting HCAHPS data that meet the requirements of the Hospital IQR Program.

We continue to strongly recommend that each new hospital participate in an HCAHPS dry run, if feasible, prior to beginning to collect HCAHPS data on an ongoing basis to meet Hospital IQR Program requirements. New hospitals can conduct a dry run in the last month of a calendar quarter. The dry run will give newly participating hospitals the opportunity to gain first-hand experience collecting and transmitting HCAHPS data without the public reporting of results. Using the official survey instrument and the approved modes of administration and data collection protocols, hospitals/survey vendors will collect HCAHPS dry-run data and submit the data to My QualityNet, the secure portion of QualityNet.

We again are encouraging hospitals to regularly check the HCAHPS Web site at *http://www.hcahpsonline.org* for program updates and information. We invite public comment on our proposal to continue using these HCAHPS requirements for the FY 2016 payment determination.

f. Proposed Data Submission Requirements for Structural Measures

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644), beginning with FY 2013, we finalized the period of data collection for which hospitals will submit the required registry participation information once annually for the structural measures via a Web-based collection tool. We finalized our proposal for FY 2014 for submission of structural measures between April 1, 2013 and May 15, 2013 with respect to the time period of January 1, 2012 through December 31, 2012. We are proposing to continue this policy for FY 2015 and subsequent years. For the FY 2015 payment determination, the period of data collection for which hospitals will submit the required registry participation information for the structural measures via a Web-based collection tool will be between April 1, 2014 and May 15, 2014, with respect to the time period of January 1, 2013 through December 31, 2013. We invite public comment on this proposal.

g. Proposed Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51644 through 51645), we adopted the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the HAI measures to NHSN. The existing data collection and submission timeframes for the HAI measures for the FY 2014 payment determination align with the submission timeframes for chart abstracted measures. The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/* . Hospitals will have until the Hospital IQR Program final submission deadline to submit their quarterly data to NHSN. After the final Hospital IQR Program submission deadline has occurred for each calendar quarter of CY 2013, for FY 2015 quarters, CMS will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

We are proposing to continue this policy, with the two exceptions discussed below, for the FY 2015 payment determination and subsequent years.

Topic	FY 2015 Payment determination: Hospital associated infection measures (CDC/NHSN)
	Central Line Associated Blood Stream Infection. Surgical Site Infection. Catheter Associated Urinary Tract Infection. MRSA Bacteremia. Clostridium difficile. Healthcare Provider Influenza Vaccination.

We realize that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting, for example, when a hospital has no ICUs. We are proposing to provide an exception for the CLABSI and CAUTI measures for hospitals that do not have an ICU, reducing the burden associated with reporting to NHSN. In addition, we recognize that some facilities may perform so few procedures requiring surveillance under the Surgical Site Infection (SSI) measure that the data may not be meaningful for *Hospital Compare* or sufficiently reliable to be utilized for payment determination. We are proposing to provide an exception for these hospitals from the reporting requirement in any given year if the hospital performed fewer than a combined total of 10 colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year. For example, a hospital that performed only 2 colon surgeries and 4 abdominal hysterectomies in 2012 would not be required to report the SSI measure in 2014. We are proposing to provide hospitals with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI and SSI measures, which will be available on QualityNet. We invite public comment on this proposal.

6. Proposed Supplements to the Chart Validation Process for the Hospital IQR Program for the FY 2015 Payment Determination and Subsequent Years

For the FY 2015 payment determination and subsequent years, we are proposing to continue using, with some modifications, the validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648). The modifications we are proposing, explained in detail below, are as follows: (a) Using separate validation approaches for chart-abstracted clinical process of care and HAI measures; (b) changing the number of hospitals included in the base annual validation random sample; and (c) using targeted selection of supplemental hospitals to be added to the base sample. As described below, these proposals are intended to strengthen the Hospital IQR Program by validating a larger set of measures, increasing opportunities to detect poor reporting through different approaches to targeting and scoring, and increasing the rigor associated with our validation process, all while ensuring that the wider scope and greater rigor only modestly increases the burden of validation activities on hospitals relative to prior years. We invite public comment on each of these proposals.

a. Separate Validation Approaches for Chart-Abstracted Clinical Process of Care and HAI Measures

(1) Background and Rationale

We finalized reporting to the Hospital IQR Program of 25 chart-abstracted measures in 7 topic areas: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); surgical care improvement project (SCIP); emergency department throughput (ED); immunization (IMM); and HAIs for the FY 2014 payment determination and subsequent years in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51628 through 51629). For the FY 2015 payment determination and subsequent years, we are proposing to continue validating the chart-abstracted clinical process of care measures with the exception of the SCP–VTE–1 measure, which we are proposing for removal from the Hospital IQR program starting with the FY 2015 payment determination. We are also proposing to continue validating the one HAI measure—CLABSI—that we finalized for validation in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51646). We also are proposing to validate two additional HAI measures, catheter-associated urinary tract infection (CAUTI) and surgical site infection (SSI), which were finalized for inclusion in the Hospital IQR Program for the FY 2014 payment determination and subsequent years in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51628 through 61629). We are proposing to add these two measures to those we validate so that we can ensure data reliability on all chart-abstracted measures on which hospitals will have been reporting data under the Hospital IQR Program for at least one year prior to the FY 2015 payment determination.

The inclusion of the three chart-abstracted HAI measures—CLABSI, CAUTI, and SSI—in the Hospital IQR Program reflects HHS' priority to increase patient safety by preventing HAIs. As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51645), the mechanism for reporting HAI measures is different from the mechanism for reporting on the chart-abstracted clinical process of care measure sets (AMI, ED, IMM, HF, PN, SCIP). In addition, the infection events for which hospitals would report on the HAI measures occur rarely relative to the events for which hospitals would report on the clinical process of care measure sets. We cannot report a single number describing the national incidence for these three HAIs collectively or individually because infection rates vary by the type of hospital, their patient populations, device utilization rates, and performance of different types of surgeries.[91] However, we know that these events are sufficiently rare that if we did not find a way to target records with a higher probability of including an HAI, many hospitals would have to submit virtually all records per quarter to effectively validate the HAI measure set. For these reasons, we are proposing, and we describe below in section VIII.A.6.a.(3) of this preamble, to separate the approaches for targeting and sampling of records for HAI validation from the approaches finalized for validation of the chart-abstracted clinical process of care measure sets in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647 through 51648), and summarized in VIII.A.6.a.(2) of this preamble, and we are proposing to calculate separate scores for the group of clinical process of care measure sets and the HAI measure set as described in VIII.A.6.a.(4) of this preamble.

[91] Dudeck MA, Horan TC, Peterson KD, *et al.* National Healthcare Safety Network (NHSN) Report, data summary for 2010, device-associated module. Am J Infect Control. 2011 Dec;39(10):798–816. Edwards JR, Peterson KD, Mu Y, *et al.* National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009. Am J Infect Control 2009 Dec; 37:783–805.

(2) Selection and Sampling of Clinical Process of Care Measures for Validation

The approach to selection and sampling of clinical process of care measure sets for validation was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) for the 2014 payment determination and subsequent years. These measures and measure sets are shown in the table below.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM CHART-ABSTRACTED CLINICAL PROCESS OF CARE MEASURES TO BE VALIDATED FOR THE FY 2014 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Topic	Measures
Acute Myocardial Infarction (AMI) Measures.	• AMI–2 Aspirin prescribed at discharge. • AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival. • AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI). • AMI–10 Statin Prescribed at Discharge.
Heart Failure (HF) Measures	• HF–1 Discharge instructions. • HF–2 Evaluation of left ventricular systolic function. • HF–3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction.
Pneumonia (PN) Measures	• PN–3b Blood culture performed in the emergency department prior to first antibiotic received in hospital. • PN–6 Appropriate initial antibiotic selection.
Surgical Care Improvement Project (SCIP) Measures.	• SCIP INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision. • SCIP INF–2 Prophylactic antibiotic selection for surgical patients. • SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery). • SCIP INF–4 Cardiac surgery patients with controlled 6AM postoperative serum glucose. • SCIP INF–9 Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero. • SCIP INF–10 Surgery patients with perioperative temperature management. • SCIP Cardiovascular-2 Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period. • SCIP INF–VTE–1 Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered.* • SCIP–VTE–2 Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery.
Emergency Department Throughput (ED) Measures.	• ED–1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital. • ED–2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status.
Prevention: Global Immunization (IMM) Measures.	• Immunization for Influenza. • Immunization for Pneumonia.

* We are proposing to remove this measure from the Hospital IQR Program starting with the FY 2015 payment determination.

We describe the validation approach for these measures, which was finalized in FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648), for informational purposes only. A total of 15 records will be selected per quarter for the chart-abstracted clinical process of care measures. Three records per quarter will be sampled from among all records submitted to the Warehouse in each of four groups defined as part of the AMI, HF, PN, and SCIP measure sets. In addition, three records per quarter will be sampled from among the remaining submissions to the Warehouse and will be validated for the ED and IMM measure sets. CMS will also abstract data regarding the ED and IMM measure sets from records submitted for the AMI, HF, PN, and SCIP measure sets.

We finalized our proposal in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51648) to abstract ED and IMM data from all cases selected from other measure sets (AMI, HF, PN, SCIP, and CLABSI). For the FY 2015 payment determination and subsequent years, we are proposing to discontinue abstracting ED and IMM data from cases selected for the CLABSI measure. We are proposing this change in order to be consistent with the policy proposed in section VIII.A.6.a.(1) of this preamble to calculate separate scores for HAI and chart-abstracted clinical process of care measure sets.

Accordingly, for the FY 2015 payment determination and future years, we are proposing to continue our current validation approach for chart-abstracted clinical process of care measures as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) with the exception of discontinuing our policy of abstracting ED and IMM cases from CLABSI records. The chart-abstracted clinical process of care measures we have previously finalized for validation for the FY 2015 and subsequent years' payment determinations are set out above.

(3) Selection and Sampling of HAI Measures for Validation

As explained in section VIII.A.6.a.(1) of this preamble, we are proposing separate selection, sampling, and validation scoring for HAI measures. The HAI measures we are proposing to validate for the FY 2015 payment determination and subsequent years are CLABSI, CAUTI, and SSI.

HAI MEASURES IN THE HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM TO BE VALIDATED FOR THE FY 2015 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Measures Continued for Validation for the FY 2014 Payment Determination

HAI MEASURES IN THE HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM TO BE VALIDATED FOR THE FY 2015 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

- Central line-associated blood stream infection (CLABSI) among intensive care unit (ICU) patients.

Additional Measures Proposed for Validation for the 2015 Payment Determination

- Surgical Site Infection (SSI) among patients with procedures for colon surgery or abdominal hysterectomy.
- Catheter-associated urinary tract infection (CAUTI) among ICU patients.

Because the events reported in the HAI measure set occur rarely, they require a targeted approach to validation. For the FY 2015 payment determination and subsequent years, we are proposing to validate these measures by identifying records that are ''candidate HAI events,'' which we define below. We would construct three separate lists of candidate events, one for each HAI measure. The proposed process to construct these lists is detailed further below. Each listing of candidate events will include both actual HAI events as well as many non-events. The purpose in creating these listings would be to identify records that are more likely to contain HAI events than CMS could obtain through a simple random sample of hospital discharges each quarter. In each case, this proposed process would minimize burden to hospitals while enriching the validation sample by targeting candidate events. As described later in this section, a combined list of candidate HAI events would be created from the three separate candidate HAI lists (for CLABSI, CAUTI, and SSI). The final list would be used to generate a random sample of medical records to be reviewed and evaluated for the presence or absence of one or more of the HAI events. We describe the proposed sample size later in this section and describe the scoring process in section VIII.A.6.a.(4) of this preamble.

We are also proposing to discontinue the practice finalized in FY 2012 IPPS/LTCH final rule (76 FR 5148) of abstracting CLABSI data from the records selected for the chart-abstracted clinical process of care measure sets (AMI, ED/IMM, HF, PN, SCIP). We are proposing this change in order to be consistent with the policy proposed in section VIII.A.6.a.(1) of this preamble to calculate separate scores for HAI and chart-abstracted clinical process of care measure sets. We invite public comment on this proposal.

We finalized a two-phase process for identifying and constructing lists of candidate CLABSI events in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648). This process is summarized for the readers' information. In the first phase, each sampled hospital quarterly provides CMS with listings of positive blood cultures drawn from ICU patients. The listings include ''all blood cultures positive for infection status taken from ICU patients conducting CLABSI surveillance [92] during the discharge quarter'' (76 FR 51646). These listings are annotated to identify each ICU patient on this list who had a central venous catheter (CVC). The listings are then reviewed by a CMS contractor who produces a list of unique episodes of care for ICU patients with a CVC and that include either at least one positive blood culture for a known pathogen, or at least two positive blood cultures for the same common commensal. A blood culture which is positive for a common commensal may reflect a contaminated sample. Therefore, when the only positive blood culture result is for a common commensal, the second culture bearing the same result must be drawn from the patient within 48 hours of the first; this would confirm that the first positive common commensal result is not a consequence of contamination. A list of common commensals is provided by CDC.[93]

We are proposing to modify this process for FY 2015 and subsequent years by requiring the Medicare health insurance claim (HIC) number to be added to the positive blood culture list if a patient has one. As explained further below, we are proposing this addition specifically so that we may identify candidate CLABSIs that we also identify as candidate SSIs. Because the candidate SSIs would be identified through claims, the HIC number is needed to match patients from the candidate CLABSI list with those from the candidate SSI list. To protect this sensitive information, we are proposing that positive blood culture lists be submitted through the Secure Data Exchange on the QualityNet Web site. We invite public comment on each of these proposed modifications to the identification of candidate CLABSI events.

For the FY 2015 payment determination and subsequent years, we are proposing to adapt the process finalized to identify candidate CLABSI events in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) to identify candidate CAUTI events. In the first stage of this process, a CMS contractor would request a listing of positive urine cultures among ICU patients from the hospitals targeted for validation. The culture list would indicate the name of each pathogen detected and the number of colony forming units per ml. For the same reasons and following the same processes as those explained for CLABSI above, we are proposing to require the hospital to report the Medicare HIC number for Medicare patients included on this list.

In the second stage of this process, the CMS contractor would apply NHSN criteria to eliminate those urine cultures that are not consistent with the definition of an ICU-associated CAUTI. The contractor would then remove duplicates from the same patient to produce a list which would include only one entry per ICU patient. Our intent is to target a set of patient discharges with a higher probability of having a CAUTI event than one could obtain from a simple random sample of patient discharges. We invite public comment on this proposal.

The final HAI measure we are proposing for targeted validation is SSI. Consistent with Hospital IQR Program reporting requirements for this measure, we are proposing that validation will target SSIs among patients with colon surgeries and abdominal hysterectomy procedures.[94] We are proposing a process for identifying candidate SSIs that is different from that which we are proposing for candidate CLABSI and CAUTI both because post-discharge follow-up is so critical to proper ascertainment and because SSIs are reported more consistently in claims data than CLABSI and CAUTI. Thus, claims data provide a resource for selecting candidate events for SSI using a methodology which limits burden to hospitals. Accordingly, we are proposing to select candidate events from among Medicare FFS claims for patients who have had colon surgeries or abdominal hysterectomies as defined by NHSN.[5] For each Medicare FFS

[92] *http://www.cdc.gov/nhsn/PDFs/FINAL-ACH-CLABSI-Guidance.pdf.*

[93] *http://www.cdc.gov/nhsn/XLS/Common-Skin-Contaminant-List-June-2011.xlsx.*

[94] *http://www.cdc.gov/nhsn/PDFs/FINAL-ACH-SSI-Guidance.pdf.*

patient who had a relevant surgery in the period under validation, a CMS contractor would review the index claim (that is, the one denoting the surgery) and all subsequent readmissions to the index hospital within a 30 day post-discharge period. To identify ''candidate SSI events,'' we would look specifically for discharge diagnoses on the index claim and all inpatient claims in the 30 days post-discharge that might indicate infection. Examples of such diagnoses include ''post-operative shock'' (ICD–9–CM: 998.0), ''post-operative wound disruption (ICD–9–CM: 998.3), and postoperative infection (ICD–9–CM: 998.5). A description of our general approach, and a list of ICD–9–CM codes which we are proposing to use to identify applicable candidate SSIs is included in Appendix 1 of ''Platt R, Kleinman K, Thompson K, et al. Using automated health plan data to assess infection risk from coronary artery bypass surgery. Emerg Infect Dis. 2002 Dec;8(12):1433–41,'' which may be accessed online at *http://www.cdc.gov/eid/content/8/12/pdfs/v8-n12.pdf*.[95]

Although diagnoses which identify candidate SSIs may also be identified during readmission to hospitals other than the index hospital, for validation of SSI for the FY 2015 payment determination, we are proposing to exclude these candidate events. We are proposing this approach because we will be unable to distinguish between a candidate SSI that the index hospital determined was not an actual SSI because it did not meet properly applied NHSN case definitions, and an actual SSI that the index hospital failed to properly identify and document. Although records from the readmitting hospital may provide evidence as to the likelihood that a candidate SSI was an actual SSI, the index hospital may not have had access to this information. Therefore, if the index hospital does not report a candidate SSI event associated with a readmission to another hospital, and also does not document this event, we do not know what information, if any, the index hospital used to assess the candidate event.

This situation arises because although our regulation at 42 CFR 482.24 requires hospitals to maintain medical records that document HAI, it does not require hospitals to document that follow-up was performed. We understand that this represents a gap in our validation program for SSI, and solicit public comments on how we might fill this gap in the future.

After identifying the three separate sets of candidate events for CLABSI, CAUTI, and SSI, we will combine the lists and remove any duplicates for a given episode of care. Removing duplicates is a standard statistical practice which is important for the accuracy of the estimates.[96] Next, we are proposing to draw a random sample of 12 candidate events per quarter from which to assess reliability of HAI reporting. Over four quarters, this would yield a sample size of 48 candidate events per year. Whenever a sample is used to estimate a statistic such as reliability for the entire population of events, that estimate is said to be made with error, commonly referred to as the margin of error. For hospitals with 480 or more candidate HAI events each year, and assuming a relatively constant number of candidates per quarter, the annual sample size will be sufficient to estimate a score of 75 percent with a margin of error plus or minus 10 points with 90 percent confidence. We believe this is the smallest sample size that would be sufficient to identify hospitals that are reporting HAI data poorly and have 480 or more candidate events.

However, if there are fewer than 480 candidate events per year, the finite population correction applies, such that the margin of error will decrease as the total number of candidate events per year gets smaller.[97] Based on our analysis of CLABSI data previously reported under the Hospital IQR Program, estimating the relative occurrence of CLABSI, CAUTI, and SSI, and allowing for the fact that there may be many candidates for every confirmed HAI, we expect that most hospitals will have fewer than 480 candidate HAI events per year (or 120 per quarter), which will allow us to estimate a score of 75 percent for these hospitals with a margin of error even less than plus or minus 10 points with 90 percent confidence.

In the event that a hospital has 12 or fewer candidate HAIs in a given quarter, it is still possible to produce accurate estimates of reliability. In quarters in which a hospital has 12 or fewer candidate HAI events, we are proposing to select all candidates, which will allow us to measure reliability without any margin of error. These quarterly estimates will have no sampling error because we will not be drawing a sample, but rather will be using the entire population for that quarter. If a hospital has 12 or fewer cases in every quarter, we may estimate reliability of HAI reporting for the year without any margin of error. If a hospital has no candidate events in the year, we would not be able to estimate a reliability rate. Therefore, as discussed in section VIII.A.6.a.(4) of this preamble, we would not attempt to estimate an HAI score for hospitals with 0 cases. We invite public comment on these proposed sample sizes.

(4) Validation Scoring for Chart-Abstracted Clinical Process of Care Measures and HAI Measures

As noted in section VIII.A.6.a.(1) of this preamble, HAIs occur rarely relative to the clinical process of care measures. The rarity of HAIs creates problems for validation scoring of this measure set. To produce an overall score that combines the scores for the individual measure sets, CMS computes a weighted average of each measure set score for each quarter.[98] The weight applied to each measure set is proportionate to the occurrence of records that were submitted to the Warehouse for that measure set. Because CLABSI, CAUTI, and SSI occur rarely, we anticipate that the total number of records targeted for validation of these measures will account for much less than 25 percent of the combined total of all records submitted to the Warehouse. Consequently, if the scores for HAI were combined with the other measure sets, a hospital could potentially report incorrectly for all HAI targeted records, and still meet our established reliability criterion of 75 percent, thus passing validation. This would mean that our process would fail to offer proper quality control for the HAI measure set. Although HAIs are rare, we believe that validation of HAI reporting is critical because it supports HHS' priority to reduce these infections.

For all of these reasons, we are proposing separate scoring processes for the HAI and chart-abstracted clinical process of care measure sets, and to require hospitals to receive passing scores on both processes to pass validation for the FY 2015 payment determination and subsequent years. We are proposing changes to our regulations at § 412.140(d)(2) to address this proposed requirement. In particular, our regulation currently states that ''A hospital meets the validation

[95] Platt R, Kleinman K, Thompson K, *et al.* Using automated health plan data to assess infection risk from coronary artery bypass surgery. Emerg Infect Dis. 2002 Dec;8(12):1433–41.

[96] ''Duplicate listings'' in Kish L. *Survey Sampling,* John Wiley & Sons, New York: 1995, pp.58–59.

[97] ''2.6 The finite population correction.'' Cochran WG. *Sampling Techniques,* third edition. John Wiley & Sons, New York, 1977, pp. 24–25.

[98] ''Confidence Interval Calculation'', *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115987129*, last accessed March 19, 2012.

requirement with respect to a fiscal year if it achieves a 75-percent score as determined by CMS.'' We are proposing to change this language to state: ''A hospital meets the validation requirement with respect to a fiscal year if it achieves a passing score, as determined by CMS, on applicable measure sets.'' We propose to define ''passing score'' to mean a score of 75-percent on both of the chart-abstracted clinical process of care and HAI measure set groupings that apply to the hospital. The proposed computation and evaluation of passing for these separate scores are described further below.

For the chart-abstracted clinical process of care measures, we are not proposing any changes to the methodology for reviewing charts, computing the score for each measure set, computing a summary score across all measure sets, or computing the variance around these summary scores. This process was described in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226).

For the FY 2015 payment determination and subsequent years, we are proposing to use the same basic approach to CLABSI scoring that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647), but to modify this scoring process to include consideration of all three HAI measures simultaneously. For example, if a sampled record is determined to include a CLABSI event and no CAUTI or SSI events, and one CLABSI event, was reported to NHSN, we are proposing to assign the record a score of 1/1. If a sampled record had two independent episodes of CLABSI, CAUTI, or SSI or a combination of infections, both events would have to be reported to NHSN to receive a score of 1/1. Similarly, if no events were reported to NHSN and the medical record indicated there were no events, we are proposing that the record would receive a score of 1/1. We are proposing to assign a score of 0/1 to a record if no event was reported to NHSN and at least one CLABSI, CAUTI, or SSI was detected, or if an event was reported but for the wrong infection. For example, if an SSI was reported to NHSN as a CLABSI, the record would receive a 0/1. We are also proposing to assign a score of 0/1 to a record if an event was reported to NHSN for CLABSI, CAUTI, or SSI, and the CMS contractor determined that there was no such event.

For the FY 2015 payment determination and subsequent years, we are proposing a slightly different process for requesting medical records for SSI. Specifically, we are proposing that when a candidate SSI is identified based on a readmission diagnosis, CDAC would request two records per candidate SSI event. This proposal is necessary because many SSIs are not diagnosed until after patient discharge. In these circumstances, the hospital might first become aware of the SSI upon readmission. Therefore, the information needed to evaluate the presence or absence of an SSI for these candidate events would be divided across two records: (1) The medical record for the hospitalization during which surgery was performed; and (2) the medical record for the readmission to treat the candidate infection. Therefore, we are further proposing for the FY 2015 payment determination and subsequent years that when a candidate SSI is identified based on a readmission diagnosis, we evaluate the occurrence of an SSI event related to the index hospitalization using data in both records. In contrast, we are proposing to limit evaluation of CLABSI and CAUTI to the record for the index hospitalization. We are proposing these changes to incorporate CAUTI and SSI into HAI scoring, which were not part of previous validation efforts. We invite comments on these proposals.

This proposed process will be used to create a mean HAI score for each hospital. The mean will equal the number of HAI records correctly classified divided by the total number of HAI records scored. As described in section VIII.A.6.a.(3) of this preamble, a sample of up to 12 records is to be drawn quarterly, for annual sample of up to 48. The approach of dividing the year into 4 quarters and drawing an independent random sample from each is known as stratified random sampling. When the validation sample includes all of the candidate HAI events that a hospital generates in a year, reliability is measured without error. In this case, the upper bound of the confidence interval will be exactly the same as the estimate of reliability. However, when this score is based on only a sample of records containing candidate HAIs, we must compute a variance around this mean. We are proposing to compute the confidence interval by applying the appropriate formula for the variance of a proportion in a stratified random sample.[99]

[99] ''Section 5.10 Stratified sampling for proportions'' in Cochran WG. Sampling Techniques, third edition. John Wiley and Sons, New York,1977, pp. 107–108.

(5) Criteria to Evaluate Whether a Score Passes or Fails

Historically, we have used two criteria for passing validation in the Hospital IQR Program, which were described in FY 2011 IPPS/LTCH PPS final rule (75 FR 50226):

- Require all Hospital IQR Program participating hospitals selected for validation to attain at least a 75-percent validation score per quarter to pass the validation requirement.
- Use the upper bound of a one-tailed 95 percent confidence interval to estimate the validation score.

For the FY 2015 payment determination and subsequent years, we are proposing to modify both of these criteria. We are proposing that hospitals achieve scores of 75 percent or higher for both the chart-abstracted clinical process of care measure grouping and the HAI score to pass validation. We are proposing to compute each score by combining the data across all four quarters, instead of by considering the quarters separately. We are proposing to make this change because 4 quarters combined can provide a more accurate estimate of reliability than could be attained from a single quarter.

We also are proposing that if hospital has no candidate CLABSI, CAUTI, or SSI in the year to be validated or a hospital has been excepted from NHSN reporting for all three HAIs, it will only be required to achieve a 75 percent score for the chart-abstracted clinical process of care measures to pass validation. We are making this proposal because, in these instances, no HAI score can be computed.

For the FY 2015 payment determination and subsequent years, we are proposing to replace the use of a one-tailed 95 percent confidence interval with a two-tailed 90 percent confidence interval. The reason for this proposal is so that we may identify hospitals passing our annual 75 percent threshold that also have scores within the statistical margin of error for not passing this annual requirement. The upper bound of a two-tailed 90 percent confidence interval is exactly the same number as the upper bound of a one-tailed 95 percent confidence interval. Therefore, this proposal will have no impact on the number of hospitals in the base annual sample that pass or fail validation. The Government Accountability Office (GAO) has noted that CMS does not have a methodology to address hospitals, for which ''the statistical margin of error for their accuracy included both passing and

failing levels.'' [100] For data included in the GAO report, one-quarter to one-third of hospitals fell into this category. CMS has subsequently taken steps to address other GAO concerns, which has reduced the percentage of hospitals that neither passed nor failed validation to 7 percent in the FY 2012 payment determination.

Nonetheless, we believe that there is value in looking more closely at the remainder of these hospitals. For the FY 2015 payment determination and subsequent years, we propose to identify those hospitals which have neither passed nor failed, using a two-tailed confidence interval. In addition, for the purpose of payment determination in FY 2015 and subsequent years, we are proposing to continue to pass these hospitals, while also targeting these hospitals for validation next year, which we are proposing in section VIII.C.6.c. of this preamble.

If, as in previous years, our only concern was in hospitals with an upper bound for the reliability rate below 75 percent, we would have 95 percent confidence in the upper bound. However, because we are proposing to identify hospitals for which ''the statistical margin of error for their accuracy included both passing and failing levels,'' we must consider both an upper and lower confidence bound. Therefore, the same interval provides only 90 percent confidence (5 percent of samples will have lower interval bounds based on the sample that are higher than the actual reliability for the population and 5 percent will have upper interval bounds that are lower than the actual reliability rate for the population). Computing a two-tailed interval and adjusting its confidence level from 95 to 90 percent is the only way to maintain the computation for the upper bound using the same formula as that used in previous years and also calculate the lower bound,[100,101] which will allow us to identify hospitals that would otherwise neither pass nor fail validation. We invite public comment on this proposal.

b. Number and Manner of Selection for Hospitals Included in the Base Annual Validation Random Sample

As finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225–50227), validation of chart-abstracted measures in the Hospital IQR Program uses a base annual random sample of 800 hospitals. For the FY 2015 payment determination and subsequent years, we are proposing to reduce the total base sample size of hospitals included in the annual validation random sample from 800 to 400. One of our goals in targeting a certain number of hospitals for our base annual random sample is to estimate the total percentage of hospitals that have been reporting unreliable data for the Hospital IQR Program. The minimum sample size required to assess the percentage of hospitals in the Hospital IQR Program have been reporting unreliable data depends on the expected percentage of hospitals that fail validation. Because a very high percentage of Hospital IQR Program hospitals pass validation (more than 99 percent of the hospitals in the FY 2012 payment determination), we believe that we can reduce burden on hospitals by selecting fewer hospitals for the base annual random sample without adversely affecting our estimate of this percentage. We are not proposing to change the criteria for selecting the annual validation random sample because we believe that these criteria are appropriate for sample selection.

For informational purposes, we are summarizing the finalized definition of a hospital eligible for validation, as provided in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227). Those eligible for validation are the subset of subsection (d) hospitals who successfully submitted ''at least one [IQR] case for the third calendar quarter of the year two years prior to the year to which the validation applies would be eligible to be selected for validation.'' For example, for the FY 2015 payment determination, we would select the sample in early 2013, and all Hospital IQR Program-eligible hospitals that submitted at least one IQR case for third quarter 2012 discharges would be eligible to be selected for validation.

c. Targeting Criteria for Selection of Supplemental Hospitals for Validation

We have established policies for supplementation to the base annual random sample of hospitals. In particular, our supplemental validation sample includes all hospitals that fail validation in the previous year (75 FR 50227 through 50229), a policy that we do not intend to change. We also finalized a policy in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51646), that the validation sample drawn for the FY 2015 payment determination and subsequent years will include in the fourth year all hospitals not randomly occurring in the sample in the previous three years to the sample. We have reassessed this policy.

We believe that we have identified an approach with comparable benefits to reliability which would have a smaller total burden to hospitals, and at less cost to CMS. Based on chance alone, we would expect that about 1,500 (slightly less than half of all IPPS-eligible) hospitals would not have been sampled in the previous three years. Of these, less than 200 would be expected to be randomly selected as part of the base validation sample of 400 hospitals for the FY 2015 payment determination. Accordingly, this means that for the FY 2015 payment determination, the supplemental sample size would be about 1,300 hospitals. To increase the sample size by 1,300 hospitals in a single year is unnecessarily burdensome; we believe we can have the same influence on hospitals that have not been recently validated simply by increasing their probability of selection through targeting in subsequent years. Therefore, for the FY 2015 payment determination and subsequent years, we are proposing to discontinue our policy of including hospitals in the supplemental validation sample in the fourth year that have not been validated in the previous three years. We are proposing, however to use the lack of recent validation as one of several targeting criteria for a supplemental random sample described further below. For the FY 2015 payment determination and subsequent years, we are proposing to add targeting criteria as a supplement to the base random sample of up to 200 additional hospitals. We believe that this proposal would improve data quality by increased targeting of hospitals with possible or confirmed past data quality issues. As finalized in the FY 2011 IPPS/LTCH PPS final rule the supplement will include all hospitals that fail validation in the previous year. In addition, we are proposing to draw a random sample of hospitals meeting one or more of the following criteria to reach a total supplemental sample size of up to 200 hospitals (including those failing). We invite public comment on the proposal to include a targeted sample, and to use the following as criteria for targeting the additional hospitals:

- Any hospital with abnormal or conflicting data patterns. An example of abnormal data pattern would be if a hospital has extremely high or extremely low values for a particular measure. Consistent with the Hospital OQR program, we propose to define an extremely high or low value as one that falls more than 3 standard deviations

[100] Government Accountability Office. ''Hospital Quality Data. CMS needs more rigorous methods to ensure reliability of publicly released data''. GAO–06–54, January 2006.

[101] ''Chapter 8 Interval estimation'' in Wonnacott TH, Wonnacott RJ. Introductory statistics for business and economics, 2nd edition, 1977, John Wiley & Sons, New York, pp.199–201, 231–232.

from the mean (76 FR 74485). An example of a conflicting data pattern would be if two records were identified for the same patient episode of care but the data elements were mismatched for primary diagnosis. Primary diagnosis is just one of many fields that should remain constant across measure sets for an episode of care. Other examples of fields that should remain constant across measure sets are patient age and sex. Frequent occurrence of these types of data conflicts may indicate larger data quality problems. Any hospital not included in the base validation annual sample and with statistically significantly more abnormal or conflicting data patterns per record than would be expected based on chance alone ($p < .05$), would be included in the population of hospitals targeted in the supplemental sample.

- Any hospital with rapidly changing data patterns. For this targeting criterion, we propose to define a rapidly changing data pattern as a hospital which improves its quality for one or more measure sets (that is, AMI, HF, PN, SCIP, ED, IMM, or HAI) by more than 2 standard deviations from one year to the next, and also has a statistically significant difference in improvement (one-tailed $p < .05$). This pattern might indicate rapid quality improvement. It may also indicate a potential change in the accuracy of the data reported, and would be worthy of targeted validation.
- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed, which could suggest that the hospital had data for relevant time periods that was not used in calculating Hospital IQR measure rates.
- Any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated. When a hospital first enters the program, its staff may need additional support/education to ensure their understanding of reporting requirements. Moreover, receiving this feedback early in a hospital's participation may ensure that good data reporting habits are established when a hospital's process may not yet be entrenched.
- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- For the FY 2016 payment determination and subsequent years, we are proposing to add to the targeting criteria proposed for the 2015 payment determination by identifying hospitals that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent. Relative to hospitals whose confidence interval lies entirely above the target reliability rate of 75 percent, a confidence interval that includes 75 percent would indicate a higher level of uncertainty as to the reliability of data for that particular hospital. This proposal is related to the proposal to produce a two-sided confidence interval (discussed in section VIII.A.6.b of this preamble). It is intended to respond to concerns that CMS does not have a methodology to address hospitals, for which ''the statistical margin of error for their accuracy included both passing and failing levels.'' The reason that we are proposing implementation of this criterion beginning with the 2016 payment determination is that it is not feasible to implement this change until after we implement changes to the confidence interval, as proposed in section VIII.A.6.b. of this preamble.

As noted above, the established procedure for drawing the base random sample involves selection of hospitals ''early'' in the calendar year two years prior to the payment determination FY 2011 IPPS/LTCH PPS final rule (75 FR 50227). For example, the base sample for the FY 2015 payment determination will be drawn early in 2013. We are proposing that the selection of hospitals targeted in the supplemental sample for the FY 2015 payment determination occur after the FY 2014 payment determination; this will separate the timing of selection of base and supplemental samples. We are proposing to do so because CMS may need extra time to review hospital data before identifying the hospitals to include in the supplemental sample. Moreover, information regarding a hospital's status as failing or passing is not known at the time the base sample is drawn.

As finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219), the quarters included in the validation effort for each year's payment determination will be the 4th calendar quarter of the year that occurs 2 years before the payment determination and the first 3 calendar quarters of the following calendar year. For example, for the FY 2015 payment determination, the quarters included in validation would be the fourth quarter of calendar year 2012 through the third quarter of calendar year 2013.

7. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2015 Payment Determination and Subsequent Years

We are proposing to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. For the FY 2014 payment determination, the submission deadline for the Data Accuracy and Completeness Acknowledgement was aligned with the final submission quarter for each fiscal year. We are proposing to continue this approach for FY 2015 and subsequent years. For example, we are proposing that the submission deadline for the Data Accuracy and Completeness Acknowledgement would be May 15, 2014, with respect to the time period of January 1, 2013, through December 31, 2013. We invite public comment on this proposal.

8. Public Display Requirements for the FY 2015 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), we continued, for the FY 2014 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for public display requirements for the FY 2012 payment determination and subsequent years. We are not proposing any changes to these requirements.

The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *http://www.hospitalcompare.hhs.gov,* but on occasion are reported on other CMS Web sites. We require that hospitals sign a Notice of Participation form when they first register to participate in the Hospital IQR Program. Once a hospital has submitted a form, the hospital is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS (72 FR 47360). Hospitals signing this form agree that they will allow us to publicly report the quality measures included in the Hospital IQR Program.

We will continue to display quality information for public viewing as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we display this information, hospitals will be permitted to review their information as recorded in the QIO Clinical Warehouse.

9. Reconsideration and Appeal Procedures for the FY 2015 Payment Determination

The Hospital IQR Program reconsideration and appeals requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651) and are found at 42 CFR 412.140(e) of our regulations. The form for reconsiderations and a detailed description of the reconsideration process are available on the QualityNet Web site at: *http://www.qualitynet.org/* > Hospitals-

Inpatient > Hospital Inpatient Quality Reporting Program > APU Reconsiderations.

10. Hospital IQR Program Disaster Extensions or Waivers

The Hospital IQR Program disaster extensions or waiver requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51652) and can be found at 42 CFR 412.140(e) and (c)(2), respectively. The forms and a detailed description of the extension or waiver process are available on the QualityNet Web site at: *http://www.qualitynet.org/* > Hospitals-Inpatient > Hospital Inpatient Quality Reporting Program.

11. Electronic Health Records (EHRs)

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged hospitals to take steps toward the adoption of EHRs (also referred to in previous rulemaking documents as electronic medical records) that will allow for reporting of clinical quality data from the EHRs directly to a CMS data repository (70 FR 47420 through 47421). We sought to prepare for future EHR submission of quality measures by sponsoring the creation of electronic specifications for quality measures under consideration for the Hospital IQR Program.

b. HITECH Act EHR Provisions

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet requirements for meaningful use of certified EHR technology, which include reporting on quality measures using certified EHR technology. With respect to the selection of quality measures for this purpose, under section 1886(n)(3)(A)(iii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. All measures must be proposed for public comment prior to their selection, except in the case of measures previously selected for the Hospital IQR Program under section 1886(b)(3)(B)(viii) of the Act.

We continue to believe there are important synergies with respect to the two programs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage the adoption and use of certified EHRs for the anticipated future reporting of clinical quality measures under the Hospital IQR Program. Through the EHR Incentive Programs we expect that the anticipated future submission of quality data through EHRs will provide a foundation for establishing the capacity of hospitals to send, and for CMS to receive, quality measures via hospital EHRs for certain Hospital IQR Program measures in the future.

The HITECH Act requires that the Secretary seek to avoid redundant and duplicative reporting, with specific reference to the Hospital IQR Program for eligible hospitals. To the extent that quality measures are included in both the Hospital IQR Program and the EHR Incentive Programs, this would mean that the Hospital IQR Program would need to transition to use of certified EHR technology rather than manual chart abstraction. We are considering what the most practical approach to effect such a transition might be. One option is to select a date after which chart-abstracted data would no longer be used in the Hospital IQR Program where it is possible to report the data via certified EHR technology. This would require sufficient advance notice to hospitals for hospitals to report the data via certified EHR technology. At that point, we believe that it is likely that nearly all IPPS hospitals will have implemented certified EHR technology as incentivized by the HITECH Act. Another option would be to allow hospitals to submit the same measure for the Hospital IQR Program based on either chart-abstraction or, when available, EHR-based reporting. This would require extensive testing to ensure equivalence given that the data for the Hospital IQR Program supports both the public reporting of such information and the Hospital VBP Program. We are concerned that this option would not be feasible.

Ultimately, we do not anticipate having two different sets of clinical quality measures for the EHR Incentive Programs and the Hospital IQR Program. Rather, we anticipate a single set of hospital clinical quality measures, most of which we anticipate would be electronically specified. We envision a reporting infrastructure for electronic submission as an additional reporting mechanism in the future, and will strive to align the hospital quality initiative programs to seek to avoid redundant and duplicative reporting of quality measures for hospitals. We note that some important Hospital IQR Program quality measures such as HCAHPS experience of care measures are based on survey data and do not lend themselves to EHR reporting. Similarly, certain outcome quality measures, such as the current Hospital IQR Program readmission measures, are based on claims data rather than clinical data. Thus, not all Hospital IQR quality measures will necessarily be capable of being submitted through EHRs. As a consequence, not all Hospital IQR Program measures would necessarily be appropriate for inclusion in the EHR Incentive Programs.

We note that the provisions in this proposed rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

B. Proposed PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added a new subsection (a)(1)(W) and new subsection (k) to section 1866 of the Act. Section 1866(k) of the Act establishes a Quality Reporting Program for a hospital described in section 1886(d)(1)(B)(v) of the Act (hereafter referred to as a ''PPS-Exempt Cancer Hospital'' or ''PCH''). Section 1866(k)(1) of the Act provides that, for FY 2014 and each subsequent fiscal year, a PCH shall submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such a fiscal year. Section 1866(k)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, each hospital described in section 1886(d)(1)(B)(v) of the Act shall submit data to the Secretary on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, specified by the Secretary.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies. The National Quality Forum (NQF) currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser,

provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development processes. We have generally adopted NQF-endorsed measures in our reporting programs. However, section 1866(k)(3)(B) of the Act provides an exception. Specifically, it provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under section 1866(k)(3)(C) of the Act, the Secretary must publish the measure selection for PCHs no later than October 1, 2012, with respect to FY 2014.

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making public the data submitted by PCHs under the PCHQR Program. Such procedures must ensure that a PCH has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished by PCHs on the CMS Internet Web site.

2. Covered Entities

Section 1886(d)(1)(B)(v) of the Act excludes particular cancer hospitals from payment under the IPPS. This proposed regulation covers only those PPS-excluded cancer hospitals meeting eligibility criteria specified in 42 CFR 412.23(f).

3. Proposed Quality Measures for PCHs for FY 2014 Program and Subsequent Program Years

a. Considerations in the Selection of the Quality Measures

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) applies. The statutory requirement under section 1866(k)(3)(B) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

As appropriate, we have developed the principles we are using for the development and use of measures for the PCHQR Program on those we are using for the Hospital IQR Program:

- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of care measures, including measures of care transitions and changes in patient functional status.
- The measure set should evolve so that it includes a focused core set of measures appropriate to the cancer hospital category that reflects the level of care and the most important areas of service and measures for cancer hospitals. Measures will address gaps in quality of cancer care.
- We also consider input solicited from the public. For instance, CMS held a Listening Session on September 8, 2011, to receive input from consumers, advocacy groups, and providers on the measures under consideration for and implementation of the PCHQR Program.
- We considered suggestions and input from a PCH Technical Expert Panel (TEP), convened by a CMS measure development contractor, which rates potential PCH quality measures for importance, scientific soundness, usability, and feasibility. The TEP membership includes health-care providers specializing in treatment of cancer, cancer researchers, consumer and patient advocates, disparities experts, and representatives from payer organizations.

Like the Hospital IQR Program, the PCHQR Program also supports the National Quality Strategy, national priorities, HHS Strategic Plans and Initiatives, CMS Strategic Plans, takes into consideration the recommendations of the Measure Application Partnership (MAP), and strives for burden reduction whenever possible. We refer readers to the discussion of these topics in section VIII.A.3.a. of this proposed rule on ''Additional Considerations in Expanding and Updating Quality Measures'' under the Hospital IQR Program.

b. Proposed PCHQR Program Quality Measures for FY 2014 Program and Subsequent Program Years

We are proposing to adopt five quality measures for the FY 2014 program and subsequent program years. Specifically, we are proposing to adopt two CDC/NHSN-based HAI quality measures (outcome measures): (1) Central Line-Associated Bloodstream Infection (CLABSI); and (2) Catheter-Associated Urinary Tract Infection (CAUTI); and three cancer process of care measures: (1) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer; (2) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer; and (3) Adjuvant hormonal therapy.

All five of these proposed measures were reviewed by the MAP, and were recommended for inclusion in the PCHQR Program. For details regarding MAP input, please refer to the MAP Pre-Rulemaking reports located at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

(1) Proposed CDC/NHSN–Based Healthcare-Associated Infection (HAI) Measures

HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[102] It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the number of days of hospitalization required for patients and add considerable health care costs.

The reduction of HAIs is a priority for HHS, as evidenced by HHS's 2009 publication of an Action Plan to Reduce HAIs.[103] To maximize the efficiency and improve the coordination of HAI prevention efforts across the Department, HHS established in 2008 a senior-level Steering Committee for the Prevention of HAIs. In 2009, a Steering Committee, which included scientists and program officials across the Government, developed the HHS Action Plan to Prevent HAIs, providing a roadmap for HAI prevention in acute care hospitals. In the first iteration of the Action Plan, the Steering Committee chose to focus on infections in acute care hospitals because the associated

[102] McKibben L, Horan T, Guidance on public reporting of healthcare-associated infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. AJIC 2005; 33:217–26.

[103] Available at: *http://www.hhs.gov/ash/initiatives/hai/actionplan/*.

morbidity and mortality were most severe in that setting and the scientific information on prevention and the capacity for measure improvement was most complete. Thus, prevention of HAIs in acute care hospitals became the first phase of the Action Plan, and it focuses on six high priority HAI-related areas.

HAIs are largely preventable with widely publicized interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, the public reporting of HAIs has been of great interest to many health care consumers and advocacy organizations because it promotes awareness and permits health care consumers to choose the hospitals with lower HAI rates, as well as gives hospitals an incentive to improve infection control efforts. We note that the House Committee on Appropriations asked in a 2009 Report that CMS include in its ''pay for reporting'' system for subsection (d) hospitals two infection control measures, one of which was a central line-associated bloodstream infections measure (H. Rep. No. 111–220, at 159 (2009)). In the Report, the Committee stated that ''[i]f the measures are included in Hospital Compare, the public reporting of the data is likely to reduce HAI occurrence, an outcome demonstrated in previous research.''

In this proposed rule, we are proposing to adopt two NQF-endorsed HAI measures as stated in the above for the FY 2014 program and subsequent program years for the PCHQR Program: (1) National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure; and (2) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure. These proposed measures were developed by the CDC and are currently collected by the CDC via the NHSN. We are proposing to adopt these two measures for several reasons. First, we believe that these measures support the National Quality Strategy priority of patient safety as these measures focus on serious infections that can prolong patient hospital stays and increase the risk of mortality.[104] Second, the Technical Expert Panel (TEP) convened by our measure development contractor identified CLABSI and CAUTI as high priority quality issues for PCHs as an important area of quality measurement and promoting potential for improved outcomes. Third, MAP reviewed these HAI measures and supported inclusion of these measures in the PCHQR Program as they address the National Quality Strategy's priority of safer care (see MAP Pre-Rulemaking Final Report at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*).

Fourth, these two HAI measures foster alignment with other our quality reporting programs. In the FY 2011 IPPS/LTCH PPS final rule, we adopted the CLABSI measure for the Hospital IQR Program. The CLABSI measure is currently being collected as part of the FY 2013 Hospital IQR measure set, and data submission on the measure began with January 2011 events.[105] In the Hospital IQR Program, collection of this measure is limited to ICU locations. This measure also has been adopted for the FY 2014 payment determination under the LTCHQR Program; for the LTCHQR Program, data collection for this measure extends to all inpatient locations in the LTCH.

In the FY 2012 IPPS/LTCH PPS final rule, we adopted the Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days for Intensive Care Unit Patients measure for both the FY 2014 Hospital IQR and LTCHQR measure sets. In the Hospital IQR Program, collection of this measure is limited to ICU locations; for the LTCHQR Program, collection of this measure extends to all inpatient locations except neonatal ICUs. This measure is a high priority HAI measure that is included among the prevention metrics established in the HHS Action Plan to Prevent HAIs, which, as we noted above, underscores the importance of reducing HAIs.

We are proposing to collect data for these two HAI measures via the NHSN, which is a secure, Internet-based surveillance system maintained and managed by CDC, and can be used by all types of health care facilities in the United States, including acute care hospitals, cancer hospitals, long term care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, and ambulatory surgery centers. The NHSN enables health care facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events.

Some States use NHSN as a means for health care facilities to submit patient-level data on measures mandated through their specific State legislation. Currently, 28 States require hospitals to report HAIs using NHSN, and CDC provides support to more than 5,000 hospitals that are using NHSN.

NHSN data collection occurs via manual data entry into a Web-based tool hosted by CDC provided without charge to providers and via electronic reporting by providers directly to NHSN. The NHSN Agreement to Participate and Consent Form specifies the purposes to which NHSN data are put, including enabling providers, such as cancer hospitals, to report data via NHSN to CMS in fulfillment of CMS's quality measurement reporting requirements for those data.

In addition, data submission for HAI measures through electronic health record technology (EHRs) may be possible in the near future and this would further reduce reporting burden on hospitals.

(A) Proposed Central Line-Associated Blood Stream Infections Measure ((CLABSI), NQF #0139)

The proposed CLABSI measure was originally developed by CDC to assess the percentage of ICU and high-risk nursery patients who, over a certain amount of days, acquired central line catheter-associated bloodstream infections. CDC recently updated this measure to expand the care setting to all inpatient settings (not just ICUs). As indicated previously, the measure has been renamed as National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure and we are proposing to adopt this measure for use for the FY 2014 program and subsequent program years. This measure is considered an outcome measure by NQF as it relates to the results of the quality of care provided to patients; it is risk adjusted by which the observed infection rate for a particular location in a hospital is compared to an expected infection rate calculated based on the specific location within other facilities that report to the NHSN. Measure specifications may be accessed at: *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*.

A central line is a catheter that health care providers often place in a large vein in the neck, chest, or groin to give medication or fluids or to collect blood for medical tests. Many patients are discharged from short-term acute care hospital intensive care units (ICUs) or ICU stepdown units with these central lines in place.

[104] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*, accessed on January 20, 2011.

[105] The CDC captures HAI data based on the onset of an event, rather than based on the discharge date.

Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality.[106] An estimated 248,000 bloodstream infections occur in U.S. hospitals each year.[107] Furthermore, despite the preventability of these infections, CLABSIs result in thousands of deaths each year and billions of dollars in added costs to the U.S. health care system, CDC is providing guidelines and tools to the health care community to help reduce central line catheter-associated bloodstream infections. CLABSIs can be prevented through proper management of the central line. CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections* recommends evidence-based central line insertion practices known to reduce the risk of subsequent central line-associated bloodstream infection.[108] These include hand-washing by inserters, use of maximal sterile barriers during insertion, proper use of a skin antiseptic prior to insertion, and allowing that skin antiseptic to dry before catheter insertion. Despite the scientific evidence supporting these practices, several reports suggest that adherence to these practices remains low in U.S. hospitals.

This measure is NQF-endorsed and, therefore, meets the requirement of section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program must be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the NHSN Central Line-Associated Bloodstream Infection (CLABSI) outcome measure for the PCHQR Program for collection in both ICU and non-ICU locations within a PCH to align with the recently-expanded NQF-endorsed measure specifications for the FY 2014 program and subsequent program years.

(B) Proposed Catheter Associated Urinary Tract Infection Measure ((CAUTI), NQF #0138)

The catheter-associated urinary tract infection (CAUTI) measure was developed by CDC to measure the percentage of patients with CAUTIs in the ICU context. CDC has recently updated the specifications of this measure to include all inpatient settings (not just ICUs). This measure has been renamed as National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and we are proposing to adopt this measure for use for the FY 2014 program and subsequent program years. This measure is considered an outcome measure as it relates to the results of the quality of care provided to patients; it is risk adjusted by which the observed infection rate for a particular location in a hospital is compared to an expected infection rate calculated based on the specific location within other facilities that report to the NHSN. Measure specifications may be accessed at: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf*.

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[109] Healthcare-associated urinary tract infections (UTIs) are commonly attributed to catheterization of the urinary tract. CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI cause discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.[110] Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections,* which includes recommendations for proper insertion techniques, including hand washing, insertion by trained staff, use of sterile gloves, drapes, sponges and antiseptic or sterile solution for cleaning and lubricant jelly for insertion.[111]

UTIs are a major cause of morbidity and mortality. The HHS Action Plan to Prevent HAIs identified catheter associated urinary tract infections as the leading type of HAI that is largely preventable, and the occurrence of which can be drastically reduced in order to reduce adverse health care related events and avoid excess costs.

This measure is NQF-endorsed and, therefore, meets the requirement of section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) outcome measure for the PCHQR Program for collection in both ICU and non-ICU locations within a facility to align with the recently expanded NQF-endorsed measure specifications for the FY 2014 program and subsequent program years.

(2) Proposed Cancer-Specific Measures

We are proposing to adopt three measures related to the treatment of colon cancer and two types of breast cancer (hormone receptor-negative and hormone receptor-positive). Specifically, these proposed measures are: (i) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (NQF #0223); (ii) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer (NQF #0559); and (iii) Adjuvant hormonal therapy (NQF # 0220). The proposed measures were developed by the American College of Surgeons/Commission on Cancer.

We are proposing to adopt these three cancer treatment-related quality measures for several reasons. First, national cancer incidence rates suggest that breast and colon cancer will become two of the more common diagnoses (in 2012, 29 percent of cancer diagnosis in females will be breast cancer, and 6 percent of cancer diagnosis in both genders will be colon cancer [112]); these cancers are also highly prevalent among Medicare beneficiaries.

[106] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*, accessed on January 20, 2011.

[107] Klevens RM, Edward JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160–166.

[108] O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, *et al.,* Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002; 51(No. RR–10:1–26).

[109] Klevens RM, Edward JR, *et al.,* Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160–166.

[110] Wong ES., Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981; 2:126–30.

[111] Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA, *et al.,* Guideline for prevention of catheter-associated urinary tract infections. Infect Control 2009; 31:319–326.

[112] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10–29.

We believe the high incidence of these types of cancer creates an opportunity for measurements to make an impact on the quality of cancer care. Second, these measures support the National Quality Strategy's priority to promote the most effective prevention and treatment practices for the leading causes of mortality due to cancer. Third, the TEP convened by our measure development contractor identified the treatment of breast and colon cancer as high priority quality issues for PCHs due to the high incidence of these types of cancers and rated these measures highest compared to other potential program measures based on an assessment of the importance, scientific acceptability, usability, and feasibility of these measures. Also, participants in a CMS-convened Listening Session on September 8, 2011 expressed support for the proposed measures. The transcript for this Listening Session can be found at *http://www.cms.gov/HospitalQualityInits/05_HospitalHighlights.asp#TopOfPage*. Fourth, the MAP reviewed these cancer-specific measures and supported inclusion of these measures in the PCHQR Program. All of the three proposed cancer-specific measures are NQF-endorsed; therefore they satisfy the requirement of section 1866(k)(3)(A) of the Act relating to the selection of endorsed measures for the PCHQR Program. Furthermore, section 1866(k)(4) of the Act provides that quality measures reported in the PCHQR Program should assess process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to PCHs. We believe these three proposed cancer-specific measures meet the above statutory criteria, as they track important processes in the treatment of colon and breast cancer.

Although these measures are not currently reported in other HHS programs, they are reported by over 1,500 cancer programs as part of their accreditation by the Commission on Cancer, a program of the American College of Surgeons (see *http://www.facs.org/cancer/ncdb/index.html*), further indicating their importance as the Commission on Cancer has taken a leading role in establishing national standards to ensure quality in the provision of cancer care.

We are proposing that PCHs would submit the data needed to calculate these measures to a CMS contractor. We believe that a CMS contractor-based data collection mechanism would reduce the potential reporting burden because currently the majority of PCHs are submitting HAI and cancer-specific measures to the appropriate entities.

(A) Proposed Adjuvant Chemotherapy Is Considered or Administered Within 4 Months (120 days) of Surgery to Patient Under the Age of 80 With AJCC III (Lymph Node Positive Colon Cancer) (NQF #0223)

This proposed measure examines whether adjuvant chemotherapy is delivered within a specified period of time after a diagnosis of colon cancer. Specifically, it looks at the proportion of patients 18–79 with AJCC Stage III (lymph node positive) colon cancer for whom adjuvant chemotherapy is considered or administered within 4 months of diagnosis. Stage III colon cancer is colon cancer that has spread outside the colon to one or more lymph nodes. The adjuvant chemotherapy measure is a process measure as it addresses whether a defined treatment was delivered to a patient; the measure is not risk adjusted by which the measure does not attempt to account for hospital patient populations or other differences between hospitals. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons at: *http://www.facs.org/cancer/ncdb/colonmeasures.pdf*. Additionally, CMS will provide a link to the specification manual on the QualityNet Web site.

Colorectal cancer plays a sizeable role in affecting both health and health care costs in the United States. The American Cancer Society estimates that 51,690 Americans will die of colorectal cancer in 2012.[113] According to the National Cancer Institute, more than $14.1 billion was spent on colorectal cancer in 2010.[114]

Appropriate treatment may improve survival rates and reduce the likelihood of costly recurrence. Strong evidence suggests that treating Stage III colon cancer patients with adjuvant chemotherapy improves overall survival and disease-free survival.[115] In addition to being supported by evidence, this measure is consistent with the National Comprehensive Cancer Network's (NCCN) guidelines for the treatment of colon cancer (COL–4: T3–4, N1–2, MO), which recommend that colon cancer patients should receive adjuvant chemotherapy.

Section 1866(k)(3)(A) of the Act requires quality measures selected for the PCHQR Program to be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under 1866(k)(3)(B) applies. This measure is NQF-endorsed and therefore, it meets the statutory endorsement requirements.

We invite public comment on our proposal to adopt the Adjuvant Chemotherapy Is Considered or Administered Within 4 Months (120 days) of Surgery to Patient Under the Age of 80 With AJCC III (lymph node positive colon cancer) measure for the PCHQR Program for the FY 2014 program and subsequent program years.

(B) Proposed Combination Chemotherapy Is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 With AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559)

This proposed measure assesses the proportion of women ages 18–69 who have their first diagnosis of breast cancer at AJCC Stage IC, II or III and whose primary tumor is hormone (estrogen and progesterone) receptor negative for whom combination chemotherapy is considered or administered within 4 months of diagnosis. Hormone receptor negative means that hormones, such as estrogen, do not drive tumor growth. This measure is a process measure as it addresses whether a defined treatment was delivered to a patient; the measure is not risk adjusted in that the measure does not attempt to account for differences in hospital patient populations or other differences between hospitals. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons, at: *http://www.facs.org/cancer/ncdb/breastmeasures.pdf*. Additionally, CMS will provide a link to the specification manual on the QualityNet Web site.

The number of deaths from breast cancer has declined while spending has increased. The American Cancer Society estimates that 39,510 Americans will die of breast cancer in 2012.[116] Spending on breast cancer care is higher than for any other type of cancer: according to the National Cancer Institute, more than $16.5 billion was

[113] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10–29.

[114] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, and Brown ML. Projections of the Cost of Cancer Care in the United States: 2010–2020. JNCI 2011; 103:117–128.

[115] André T, Boni C, Navarro M, *et al.* Improved Overall Survival With Oxaliplatin, Fluorouracil, and Leucovorin As Adjuvant Treatment in Stage II or III Colon Cancer in the MOSIAC Trial. J Clin Onc 2009; 27:3109–3116.

[116] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10–29.

spent on breast cancer care in 2010.[117] Evidence shows that treating hormone receptor negative breast cancer patients with combination chemotherapy is associated with a reduced risk of relapse or death.[118] This measure is also consistent with NCCN's guidelines for the treatment of invasive breast cancer (BINV–4, 7–8), which recommend adjuvant chemotherapy for patients with hormone receptor negative tumors, and therefore the measure aligns with recognized standards of treatment.

This measure is NQF-endorsed and therefore, it meets the requirements under section 1866(k)(3)(A) of the Act which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 With AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559) quality measure for the PCHQR Program for the FY 2014 program and subsequent program years.

(C) Proposed Adjuvant Hormonal Therapy (NQF #0220)

This proposed measure assesses whether recommended treatment is delivered within a specified period of time from a patient's breast cancer diagnosis. Specifically, it tracks the proportion of eligible women 18 years or older who have their first diagnosis of breast cancer at AJCC T1c or Stage II or III and whose primary tumor is hormone (estrogen or progesterone) receptor positive breast cancer for whom tamoxifen or a third generation aromatase inhibitor is considered or administered within 1 year of diagnosis. Hormone receptor positive means that estrogen or progesterone promotes the growth of cancer cells. This measure is a process measure as it relates to whether a defined treatment was delivered to a patient; it is not risk adjusted. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons, at: *http://www.facs.org/cancer/ncdb/breastmeasures.pdf*. Additionally, we will provide a link to the specification manual on the QualityNet Web site.

The American Cancer Society estimates that two-thirds of breast cancer cases are hormone receptor positive.[119] As stated previously, appropriate and effective treatment is important to both the health and cost outcomes of breast cancer care. The measure is consistent with NCCN's guidelines (BINV–5, 6 and 9 and BINV–E) for the treatment of invasive breast cancer, which recommend hormone therapy for patients with hormone receptor positive breast cancer, and with the American Society of Clinical Oncology's (ASCO) Update on adjuvant endocrine therapy for women with hormone receptor positive breast cancer. The ASCO guideline cites a wide body of supporting evidence for this method of treatment.

This measure is NQF-endorsed and therefore, it meets the requirement under section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the Adjuvant hormonal therapy measure for the PCHQR Program for the FY 2014 program and subsequent program years.

In summary, we are proposing to adopt five quality measures for the PCHQR Program for the FY 2014 program and subsequent program years (listed in the table below): (1) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (data submission for ICU and non-ICU locations via CDC/NHSN); (2) NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (data submission for ICU and non-ICU locations via CDC/NHSN); (3) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (data submission to CMS contractor); (4) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer (data submission to CMS contractor); and (5) Adjuvant hormonal therapy (data submission to CMS contractor). We invite public comment on these proposed measures for the FY 2014 program and subsequent program years. The proposed details regarding data submission for these measures are covered in section VIII.B. of this preamble.

Topic	Proposed measures for PCHQR program beginning with FY 2014 program and subsequent program years
Safety and Healthcare Acquired Infections—HAI.	• NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure. • NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure.
Cancer-Specific Treatments	• Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer. • Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer. • Adjuvant Hormonal Therapy.

4. Possible New Quality Measures Topics for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the cancer hospital setting. Therefore, through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain cancer services through the widespread dissemination and use of performance information. Additionally, we are considering initiating a call for input to assess the following measure domains: Clinical quality of care, care coordination, patient safety, patient and caregiver experience of care, population/

[117] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, and Brown ML. Projections of the Cost of Cancer Care in the United States: 2010–2020. J Natl Cancer Inst 2011; 103:117–128.

[118] Fisher B, Jeong JH, Anderson S, *et al.:* Treatment of axillary lymph node-negative, estrogen receptor-negative breast cancer: updated findings from National Surgical Adjuvant Breast and Bowel Project clinical trials. J Natl Cancer Inst 96 (24): 1823–31, 2004.

[119] American Cancer Society. Breast Cancer Hormone Therapy. *http://www.cancer.org/Cancer/BreastCancer/DetailedGuide/breast-cancer-treating-hormone-therapy* Last revised 01/06/2012.

community health and efficiency. We believe this approach will promote better cancer care while bringing the PCHQR Program in line with other established quality reporting and performance improvement programs such as the Hospital IQR, the Hospital OQR, the ESRD QIP, and others within CMS' purview.

We welcome public comment and suggestions for these, or other, measurement areas.

5. Maintenance of Technical Specifications for Quality Measures

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the PCHQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the CMS QualityNet Web site at *https://www.QualityNet.org*. We would provide sufficient lead time for PCHs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF-endorsed PCH measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

Additionally, we will provide a Specifications Manual that will contain links to measure specifications, data abstraction information, data submission information, and other information necessary for PCHs to participate in the PCHQR Program. This manual would be posted on the QualityNet Web site at: *https://www.QualityNet.org*. We would maintain the technical specifications for the quality measures by updating this manual periodically, which would include detailed instructions for PCHs to use when collecting and submitting data on the required measures. These updates would be accompanied by notifications to PCHQR Program-participating users, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems. We would revise the Specification Manual and provide links to reflect such endorsement changes which also would be posted on the QualityNet Web site at: *https://www.QualityNet.org*. We invite public comment on the previously described proposed policy on maintenance of technical specifications for quality measures.

6. Proposed Public Display Requirements for the FY 2014 Program and Subsequent Program Years

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures shall ensure that a PCH has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospital on the CMS Internet Website. In order to meet these requirements, we are proposing to publicly display the submitted data on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*). Before the data are publicly displayed, we propose that PCHs will have the opportunity to review their data prior to the public reporting of the measure rates consistent with section 1866(k)(4) of the Act. We are proposing that PCHs have the opportunity to review their data 30 days prior to the public reporting of the measure rates because we would continue our current practice of preview reporting data for the PCHQR program in alignment with the HIQR program.

The Hospital Compare Website serves to encourage consumers to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish.

However, some information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations that may not make them suitable for inclusion on the Hospital Compare Web site may be made available on other CMS Web sites, such as *http://www.cms.gov* and/or *http://www.qualitynet.org*. In such circumstances, affected parties would be notified via CMS listservs, CMS e-mail blasts, and QualityNet announcements regarding the release of confidential hospital-specific preview reports to individual hospitals followed by the posting of data on a CMS Web site other than Hospital Compare.

We invite public comment on the previously described proposals regarding the public display of quality measures.

7. Proposed Form, Manner, and Timing of Data Submission for FY 2014 Program and Subsequent Program Years

a. Background

Section 1866(k)(2) of the Act requires that, for the FY 2014 program and each subsequent program year, each PCH must submit to the Secretary data on quality measures established under section 1866(k)(3) of the Act in a form and manner, and at a time as specified by the Secretary.

The complete data submission requirements and submission deadlines will be posted on the QualityNet Web site at: *http://www.QualityNet.org/*. In general, we are proposing that PCHs

submit data to the CDC for the HAI measures (CLABSI and CAUTI), and the CMS contractor for the three Cancer-Specific measures (Adjuvant Chemotherapy for Stage III Colon Cancer; Combination Chemotherapy for AJCC T1c or Stage II or III Hormone Receptor-Negative Breast Cancer; and Hormone Therapy for AJCC T1c or Stage II or III Hormone Receptor-Positive Breast Cancer). As set forth below, we are proposing to utilize the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the proposed HAI measures to NHSN. We refer readers to the CDC's website for detailed data submission and reporting procedures. We are also proposing procedures for PCHs to follow when submitting data on the three proposed cancer-specific measures.

b. Proposed Procedural Requirements for FY 2014 Program and Subsequent Program Years

In order to participate in the PCHQR Program for the FY 2014 program and subsequent program years, we are proposing that PCHs must comply with the procedural requirements outlined in this section. We have aligned these proposed procedural requirements with the Hospital IQR Program to the extent possible to streamline the procedural requirements across different types of providers. We are proposing that PCHs must do the following:

- Register with QualityNet before participating PCHs begin reporting and regardless of the method used for submitting the data.
- Identify QualityNet Administrator(s) who follows the registration process located on the QualityNet Website (*http://www.QualityNet.org*).
- PCHs participating in the PCHQR Program must complete an online Data Accuracy and Completeness Acknowledgement (DACA) via QualityNet, which states that the quality measure results and any and all data including numerator and denominator data provided, are accurate and complete. We are proposing that the time period for submitting the DACA would be August 31 of the preceding fiscal year. For more information on DACA, please refer to the section below entitled, ''Proposed Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2014 Program and Subsequent Program Years.''
- Enroll in CDC/NHSN and register with the CMS contractor collecting the Cancer-Specific measures before participating PCHs begin reporting.

We strongly encourage PCHs to complete an online Notice of Participation (NOP) via QualityNet. This form would grant CMS written authorization from the PCH to publicly report the PCH's measure rate on a CMS Web site.

PROPOSED CMS NOTICE OF PARTICIPATION TIMEFRAME

Program year (fiscal year)	Notice of participation (NOP) deadline
FY 2014	August 15, 2013.
FY 2015	August 15, 2014.
Subsequent Fiscal Years.	August 15 of the preceding fiscal year.

c. Proposed Reporting Mechanisms for FY 2014 Program and Subsequent Program Years

For the purpose of reporting quality measures under the PCHQR Program, we are proposing to adopt the following data submission mechanisms. With respect to the proposed HAI measures (CLABSI and CAUTI), we are proposing that PCHs submit the data to the CDC through the NHSN database. We are proposing to utilize the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the proposed HAI measures to NHSN. We refer readers to the CDC's website (*http://www.cdc.gov/nhsn/*) for detailed data submission and reporting procedures. After the final submission deadline has passed, CMS will obtain the PCH-specific calculations that have been generated by the NHSN for the PCHQR Program.

With respect to the three proposed (3) cancer-specific measures, we are proposing that PCHs submit the data to the CMS contractor. The CMS Contractor would then calculate the quality measures rates and submit those rates to CMS on a quarterly basis.

We invite public comment on our proposed reporting mechanisms.

(1) Proposed Reporting Mechanism for the Proposed HAI Measures

We are proposing to adopt a quarterly submission process for the proposed HAI measures –CLABIS AND CAUTI, that use similar reporting mechanism to the one finalized for the Hospital IQR program (75 FR 50223) starting with October 1, 2012 infection events. We have successfully implemented this reporting mechanism in the Hospital IQR program and intend to use similar reporting mechanism to collect data for the PCHQR program. We welcome comment on this proposal.

(2) Proposed Reporting Mechanism for the Proposed Cancer-Specific Measures

We are proposing to collect the three cancer-specific measures data using a CMS contractor starting with the FY2014 program. Similar to the reporting mechanism we are proposing to adopt for the proposed HAI measures, we anticipate that PCHs would report their measure data to the contractor, which would then calculate the measure rates and submit those rates to CMS. Should these proposed measures be finalized, we will publish the technical specifications and file layouts necessary for reporting in enough time to enable PCHs to incorporate any necessary changes to their information systems. We invite public comment on our proposed reporting requirements.

d. Proposed Data Submission Timelines for FY 2014 Program and Subsequent Program Years

We are proposing that PCHs must adhere to the following timelines in reporting their measure data:

Time line (calendar year)	Quality measures *	CMS submission deadline
Q4 (October–December 2012)	NHSN CLABSI Outcome Measure **	May 15, 2013.
	NHSN CAUTI Outcome Measure **	May 15, 2013.
	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer +.	August 15, 2013.
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer +.	August 15, 2013.
	Adjuvant Hormonal Therapy +	May 15, 2014.
Q1 (January–March 2013)	NHSN CLABSI Outcome Measure **	August 15, 2013.
	NHSN CAUTI Outcome Measure **	August 15, 2013.

Time line (calendar year)	Quality measures *	CMS submission deadline
	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer +.	November 15, 2013.
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer +.	November 15, 2013.
	Adjuvant Hormonal Therapy +	August 15, 2014.
Subsequent calendar quarters	NHSN CLABSI Outcome Measure **	November 15 of each respective year.
	NHSN CAUTI Outcome Measure **	November 15 of each respective year.
	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer +.	February 15 of each respective year.
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer +.	February 15 of each respective year.
	Adjuvant Hormonal Therapy +	November 15 of each respective year.

* Referred to as the HAI and Cancer-Specific Treatment Quality Measures.
** HAI event occurred in applicable quarter.
+ Initial diagnosis in applicable quarter.

Our principal rationale for these proposed timeframes is to align the HAI measure submission deadlines with existing CMS deadlines to collect the same quality measure information. We also seek to align our timeframes with those of the ACoS, which separately collects the same type of cancer-specific measure data from many PCHs. By aligning these deadlines by measure, we strive to reduce burden by using information already collected by many PCHs in their own quality measurement and improvement efforts. The proposed quarterly CDC/NHSN submission timeframes and deadlines also match the existing Hospital IQR quarterly submission timeframes for the same HAI measure. In the case of the three cancer-specific quality measures, we also believe that these proposed submission timeframes will give PCHs enough time to measure follow-up chemotherapy (4 months following the cancer diagnosis) and hormone therapy visits (12 months following the cancer surgery), as well as identify and correct discordant submitted data (2 months for the two proposed chemotherapy measures, and 3 months for the proposed adjuvant hormone therapy measure).

We invite public comment on the proposed data submission methods and timelines.

e. Proposed Data Accuracy and Completeness Acknowledgement (DACA) Requirements for FY 2014 Program and Subsequent Program Years

We are proposing to require PCHs to electronically acknowledge their data accuracy and completeness once annually. PCHs would submit an electronic acknowledgement that the data provided to meet the applicable annual PCHQR Program data submission requirement is accurate and complete to the best of the facility's knowledge at the time of data submission. We are proposing to begin annual DACA submission starting with the FY 2015 program, and such submission deadline would be due to CMS no later than August 31, 2014. We are proposing to begin the DACA with the FY 2015 program in an effort to provide ample opportunity for the PCHs to become familiar with the reporting processes. Therefore, we are not proposing submission of a DACA for the FY 2014 PCHQR Program. We are proposing that the DACA submission deadline for each program year be August 31 preceding the respective PCHQR Program year. We are proposing August 31 as the DACA deadline for several reasons. First, requiring PCHs to acknowledge their data's accuracy and completeness by August 31 preceding the respective PCHQR Program year provides us with sufficient time to ensure compliance with the program by October 1, the start of the fiscal year. Second, we believe it is appropriate to make the deadline for DACA the same as the deadline for data submission. Lastly, we are proposing to align our DACA deadline with other quality reporting programs, such as the Hospital IQR Program.

PROPOSED CMS DATA ACCURACY AND COMPLETENESS ACKNOWLEDGEMENT (DACA) TIMEFRAME

Program year (fiscal year)	Data accuracy and completeness acknowledgement (DACA) deadline
FY 2014	Not required.
FY 2015	August 31, 2014.
Subsequent Fiscal Years.	August 31 of the preceding fiscal year.

We invite public comments on our proposed data accuracy and completeness acknowledgement requirements.

C. Hospital Value-Based Purchasing (VBP) Program

1. Statutory Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act states that the Hospital VBP Program applies to payments for hospital discharges occurring on or after October 1, 2012. In accordance with section 1886(o)(6)(A) of the Act, we are required to make value-based incentive payments under the Hospital VBP Program to hospitals that meet or exceed performance standards

for a performance period for a fiscal year. As further required by section 1886(o)(6)(C)(ii)(I) of the Act, we will base each hospital's value-based payment percentage on the hospital's Total Performance Score (TPS) for a specified performance period. In accordance with section 1886(o)(7) of the Act, the total amount available for value-based incentive payments for a fiscal year will be equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as estimated by the Secretary. For FY 2013, the available funding pool will be equal to 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary, and the size of the applicable percentage will increase to 1.25 percent for FY 2014, 1.50 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and successive fiscal years.

Section 1886(o)(1)(C) of the Act generally defines the term ''hospital'' for purposes of the Hospital VBP Program as a subsection (d) hospital (as that term is defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term ''hospital,'' with respect to a fiscal year: (1) A hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the FY 2013 Hospital VBP Program

In April 2011, we issued the Hospital Inpatient VBP Program final rule to implement section 1886(o) of the Act (76 FR 26490 through 26547). As described more fully in that final rule, for the FY 2013 Hospital VBP Program, we adopted 13 measures, including 12 clinical process of care measures and 8 dimensions from the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS), that we categorized into two domains (76 FR 26495 through 26511). We grouped the 12 clinical process of care measures into a clinical process of care domain, and placed the HCAHPS survey measure into a patient experience of care domain. We adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these measures (76 FR 26494 through 26495), and performance standards on which hospital performance will be evaluated. To determine whether a hospital meets or exceeds the performance standards for these measures, we will assess each hospital's achievement during this specified performance period, as well as its improvement during this period as compared with its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We will then calculate a TPS for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights will be clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We will convert each hospital's TPS into a value-based incentive payment percentage using a linear exchange function and will then convert the value-based incentive payment percentage into a per discharge value-based incentive payment amount. We will incorporate the reduction to each hospital's base operating DRG payment amount for each discharge, as well as the value-based incentive payment amounts that the hospital earned as a result of its performance (if applicable) into our claims processing systems in January 2013, and these adjustments will apply to FY 2013 discharges. We refer readers to the Hospital Inpatient VBP Program final rule for further explanation of the details of the FY 2013 Hospital VBP Program (76 FR 26490 through 26547).

3. FY 2014 Hospital VBP Program Measures

For FY 2014, we have adopted 17 measures for the Hospital VBP Program, including the 12 clinical process of care measures and the HCAHPS measure that we adopted for the FY 2013 program, 1 new clinical process of care measure (SCIP–Inf–9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2), and 3 mortality outcome measures (Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, Heart Failure (HF) 30-Day Mortality Rate, Pneumonia (PN) 30-Day Mortality Rate). The clinical process of care, HCAHPS, and mortality measures are discussed in more detail in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26511) and SCIP–Inf–9 is discussed in more detail in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74530). We are proposing to codify this for quality measures selection in our regulations at 42 CFR 412.164.

Although we also previously adopted 8 HAC measures, 2 AHRQ composite measures, and a Medicare Spending Per Beneficiary Measure for the FY 2014 program, we have suspended the effective date of these measures, with the result that these measures will not be included in the FY 2014 Hospital VBP Program (76 FR 74528 through 74530).

Set out below is a complete list of the measures adopted for the FY 2014 Hospital VBP Program:

CLINICAL PROCESS OF CARE, PATIENT EXPERIENCE OF CARE AND OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

IV. Measure ID	Measure description
Clinical Process of Care Measures	
Acute myocardial infarction:	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
Heart Failure:	
HF–1	Discharge Instructions.
Pneumonia:	
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.

CLINICAL PROCESS OF CARE, PATIENT EXPERIENCE OF CARE AND OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM—Continued

IV. Measure ID	Measure description
Healthcare-associated infections:	
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
SCIP–Inf–9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2.
Surgeries:	
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience of Care Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.*
Outcome Measures	
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate.
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate.
MORT–30 PN	Pneumonia (PN) 30-Day Mortality Rate.

*The finalized dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions that we adopted for the FY 2013 program.

4. Other Previously Finalized Requirements for the Hospital VBP Program

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74547), we finalized a number of other policies for the FY 2014 Hospital VBP Program including: The minimum number of cases that a hospital must report to receive a score on a mortality measure; the minimum number of measures that a hospital must report in order to receive a score on the outcome domain; the baseline and performance periods; the performance standards for the clinical process of care and patient experience of care measures (we previously finalized the performance standards for the 3 mortality outcome measures in the Hospital Inpatient VBP Program final rule (76 FR 26513)); the scoring methodology; and the domain weighting methodology. We also finalized for all years of the program a process that will allow hospitals to review and correct the data that they submit to the QIO Clinical Warehouse on clinical process of care measures, their clinical process of care measure rates, their HCAHPS data, and their patient-mix and mode adjusted HCAHPS scores.

5. Proposed Hospital VBP Program Payment Adjustment Calculation Methodology

a. Proposed Definitions of the Term ''Base Operating DRG Payment Amount'' for Purposes of the Hospital VBP Program

Section 1886(o)(7)(D) of the Act generally defines the base operating DRG payment amount, with respect to a hospital for a fiscal year, as ''the payment amount that would otherwise be made under section 1886(d) (determined without regard to subsection (q) [the Hospital Readmissions Reduction Program]) for a discharge if [the Hospital VBP Program] did not apply; reduced by any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d); and * * * such other payments under subsection (d) determined appropriate by the Secretary.'' Paragraphs (5)(A), (5)(B), (5)(F), and (12) of section 1886(d) of the Act refer to outlier payments, indirect medical education (IME) payments, disproportionate share (DSH) payments, and low-volume hospital payments, respectively.

The payment that would otherwise be made with respect to a discharge is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii), which is often referred to as the ''the wage-adjusted DRG operating payment.'' The payment amount that would otherwise be made with respect to a discharge also includes any adjustments to the wage-adjusted DRG operating payment that the hospital qualifies for, including an outlier adjustment (under section 1886(d)(5)(A) of the Act) an IME adjustment (under section 1886(d)(5)(B) of the Act), a disproportionate share payment adjustment (under section 1886(d)(5)(F) of the Act); a low-volume payment adjustment (under section 1886(d)(12) of the Act), an adjustment for new medical services or technologies under section 1886(d)(5)(K) of the Act (often referred to as ''new technology add-on payments''), and/or any other adjustment determined appropriate by the Secretary.

Consistent with section 1886(o)(7)(D) of the Act, we are proposing to generally define the term ''base operating DRG payment amount'' for purposes of the Hospital VBP Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payment. We are proposing to include the new technology add-on payment amount in the definition of base operating DRG payment amount for the Hospital VBP Program because the provision of a new technology to a Medicare beneficiary is a treatment

decision, unlike the other add-on payments which are excluded by statute (for example, IME and DSH add-ons). We believe that it represents a cost to the Medicare program that should be subject to the applicable percent reduction to the base operating DRG payment amount which creates the funding pool for value-based incentive payments. We also note that this proposed definition is consistent with the definition of ''base operating DRG payment amount'' that we are proposing to adopt for the Hospital Readmissions Reduction Program, and we believe that maintaining consistency to the extent possible with other Medicare incentive payment programs is an important goal for the Hospital VBP Program. There are no other subsection (d) payment adjustments that would otherwise apply to the discharge on a per-claim basis. As required by the statute, the ''base operating DRG payment amount'' would not include an outlier, IME, DSH, or low-volume payment adjustment that would otherwise apply to the discharge.

We are proposing to codify the definition of wage-adjusted DRG payment amount and the general definition of base-operating DRG payment amount in our regulations at § 412.160. We welcome public comment on these proposed definitions.

Section 1886(o)(7)(D)(ii)(I) of the Act states that in the case of a Medicare-dependent, small rural hospital (MDH) (with respect to discharges occurring during FY 2012 or FY 2013) or a sole community hospital (SCH), the base operating DRG payment amount is defined as the payment amount that would otherwise be made under section 1886(d) without regard to certain factors that affect payments to these categories of hospitals (sections 1886(b)(3)(I) and (L) of the Act, and section 1886(d)(5)(D) of the Act for SCHs, and section 1886(d)(5)(G) of the Act for MDHs). Consistent with the definition we are proposing to adopt for other subsection (d) hospitals, we are proposing to define the term ''base operating DRG payment amount'' for MDHs and SCHs as the wage-adjusted DRG operating payment amount plus any applicable new technology add-on payment. The proposed base operating DRG payment amount for SCHs and MDHs would not include an outlier, IME, DSH, and/or low-volume payment adjustment that would otherwise apply to the discharge. The base operating DRG payment amount for SCHs and MDHs would not include an outlier, IME, DSH, and/or low-volume payment adjustment that would otherwise apply to the discharge. Consistent with section 1886(o)(7)(D)(ii)(I) of the Act, we are also proposing to exclude from this definition of base operating DRG payment amount the difference between the hospital-specific payment rate and the Federal rate payment. This proposed definition is consistent with that being proposed under the Hospital Readmissions Reduction Program (discussed in section IV.A. of this preamble). We are proposing to codify this definition in our regulations at 42 CFR 412.160.

We welcome public comment on this proposed definition of the base operating DRG payment amount for MDHs and SCHs under the Hospital VBP Program. We note that, under current law, the MDH program is set to expire at the end of FY 2012, after which all MDH hospitals would be paid in the same manner as other subsection (d) hospitals, unless they qualify for SCH status, as discussed in section VIII.C.5.b. of this preamble.

Section 1886(o)(7)(D)(ii)(II) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, ''the term 'base operating DRG payment amount' means the payment amount under that section.'' Acute care hospitals located in the State of Maryland are not paid under the IPPS but are, instead, paid under a special waiver provided by section 1814(b)(3) of the Act. For these hospitals, we are proposing that the term ''base operating DRG payment amount'' means the payment amount under section 1814(b)(3) of the Act. This proposed definition is consistent with the definition we are proposing under the Hospital Readmissions Reduction Program (discussed in section IV.A.. of this preamble). We are proposing to codify this definition in our regulations at 42 CFR 412.160. We welcome public comment on the proposed definition of base-operating DRG payment amount for Maryland hospitals under the Hospital VBP Program.

b. Proposals for Calculating the Funding Amount for Value-Based Incentive Payments Each Year

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. To implement these sections, and create the funding pool for value-based incentive payments for each fiscal year, we are proposing that beginning with FY 2013 discharges, every hospital that meets the definition of a hospital in section 1886(o)(1)(C) of the Act (referred to here as an eligible hospital) would receive a reduction to its base operating DRG payment amount for each discharge in a fiscal year, regardless of whether we have determined that the hospital has earned a value-based incentive payment for that fiscal year. The total amount of the reductions across all eligible hospitals for a fiscal year would constitute the total amount available from which we could make value-based incentive payments for that fiscal year. We are proposing to estimate the total amount of the reductions across all eligible hospitals and the size of the funding pool prior to the start of each fiscal year because that is the only way, operationally, that we can calculate each hospital's value-based incentive payment percentage in a manner such that the estimated sum total of the value-based incentive payments for hospitals for the fiscal year would be equal to the estimated total amount available for value based incentive payments to all eligible hospitals.

The data we are proposing to use to estimate these amounts is inpatient claims data from the Medicare Provider Analysis and Review (MedPAR) file. We believe that the use of MedPAR data is appropriate because we also use this data to calculate other IPPS payment adjustment amounts, including the DRG relative weights, budget neutrality factors, outlier thresholds, and standardized amounts. The proposed use of claims data from the MedPAR file is also consistent with our proposal in this proposed rule to determine applicable hospitals' base operating DRG payment amounts, for purposes of calculating their aggregate payments for excess readmissions and aggregate payments for all discharges for determining the readmissions payment adjustment factor under the Hospital Readmissions Reduction Program (section IV.A. of this preamble).

We are proposing to run the MedPAR data for purposes of estimating the base operating DRG payment reduction amounts, as well as the size of the funding pool that will apply to a fiscal year, in December of the previous fiscal year so that we can provide preliminary estimates in the IPPS/LTCH PPS proposed rule. We are also proposing to provide the final estimates in the IPPS/LTCH PPS final rule using the March update. The data will contain inpatient claims information related to discharges from the fiscal year that ended the previous September. For example, with respect to the FY 2014 Hospital VBP Program, we would run the MedPAR

data in December, 2012 and that data would contain claims related to FY 2012 discharges. We would use that data to provide preliminary estimates in the FY 2014 IPPS/LTCH PPS proposed rule. The March 2013 update of this MedPAR data would then be used to provide final estimates in the FY 2014 IPPS/LTCH PPS final rule.

We believe that this proposed approach will enable us to gather the most recent Medicare utilization data available in order to estimate the total amount of the base operating DRG payment amount reductions and the size of the value based incentive payment funding pool for the applicable fiscal year. We also believe that this approach will enable us to calculate each hospital's payment adjustment factor that will apply to its discharges in the applicable fiscal year, and to notify each hospital of such at the same time that we are proposing to notify each hospital regarding its performance, for purposes of making this information publicly available under section 1886(o)(10)(A) of the Act. In this way, hospitals will be able to consider this information during the review and correction period (the details of which are proposed below). We believe that it is important to notify a hospital of its value-based incentive payment adjustment factor at the start of review and corrections, so that hospitals can consider the payment impact of the TPS in their determination of whether or not to request review and corrections.

In order to estimate the total base operating DRG payment reductions across all hospitals for a fiscal year, we are proposing to sum the estimated total base operating DRG payment amount per discharge for each hospital in that fiscal year. We would then multiply that estimated total annual base operating DRG payment amount by the applicable percent, which we are proposing to define in our regulations at § 412.160 as the percentage specified in section 1886(o)(7)(C) of the Act. The product of the estimated total annual base operating DRG amount for a hospital and the applicable percent would be equal to taking the applicable percent reduction from each individual base operating DRG payment amount per hospital and then summing those reductions. We welcome public comment on this proposed approach to calculating the available pool of funds for value-based incentive payments.

For the purpose of estimating the total amount available for value-based incentive payments for a fiscal year, we are proposing to apply an inflation factor so that our estimate of the available pool of funds will more accurately reflect estimated total base operating DRG payments in the fiscal year in which the value-based incentive payments will actually be made. For example, in estimating the size of the FY 2013 funding pool, we inflated the FY 2011 MedPAR data to FY 2013 dollars because the value-based incentive payment amounts will actually be paid in FY 2013.

Our actuaries provided us with this inflation factor, which included assumptions on changes in Medicare fee-for-service case mix and discharge levels. According to this proposed methodology, we estimate the available amount for FY 2013 value-based incentive payments to be $956 million. As noted above, under our proposed methodology, we would update this estimate using the March 2012 update of the FY 2011 MedPAR data for purposes of finalizing it in the FY 2013 IPPS/LTCH PPS final rule.

We note that, for the purposes of calculating the value-based incentive payment adjustment factors under the Hospital VBP Program, we would be able to use FY 2011 claims to accurately calculate the value-based incentive payment percentage, without application of this inflation factor. This is because a constant inflation factor applied across all hospitals' total annual base-operating DRG payment amounts would not change the slope of the payment exchange function which we previously adopted for use in determining each hospital's value-based incentive payment amount. Application of an inflation factor would, therefore, not impact the amount of a hospital's value-based incentive payment amount under the Hospital VBP program for the fiscal year.

We considered adopting a different approach that would apply only to the FY 2013 Hospital VBP Program because we do not anticipate beginning to make value-based incentive payments to hospitals for that program year until January 2013. Under this approach, we would estimate the total amount of funding available to make the value-based incentive payments using the latest available FY 2011 claims data from MedPAR, with payment amounts modeled using the rates, factors and policies finalized in the FY 2013 IPPS/LTCH PPS final rule. This data would include claims information that was not available at the time we ran the March update. However we are not proposing to adopt this approach because we believe that is important to establish a consistent process for annually estimating the total amount available to make value-based incentive payments to hospitals, as well as the payment adjustments that will be made to hospitals as a result of their performance under the Hospital VBP Program. Beginning with the FY 2014 Hospital VBP Program, we intend to make the value-based incentive payments to hospitals as part of the claims payment process, beginning at the start of the fiscal year, so it would not be possible to use the modeled base-operating DRG payment amount estimates based on the finalized rates, factors and policies established in the IPPS/LTCH PPS final rule applicable to the fiscal year, as they will typically not be finalized in time to notify hospitals of their value-based incentive payment adjustments at the start of the review and corrections process.

Further, these factors, rates, and policies would not typically be finalized in time for us to notify hospitals of the net result of the base operating DRG payment amount reduction and the value-based incentive payment adjustment no later than 60 days prior to the start of the fiscal year, as required by section 1866(o)(8) of the Act. We also believe that our proposal to use the March update of the MedPAR file represents an accurate estimate of annual base operating DRG amounts because it reflects the most recently available utilization data, while preserving the interest in notifying hospitals of the payment impact in time for them to request review and correction.

We are proposing to use a different methodology for purposes of estimating the reduced annual base operating DRG payment amounts for SCHs and MDHs. In general, eligible hospitals in the Hospital VBP Program include SCHs and current MDHs (we note that MDH status is set to expire under current law after FY 2012 and would, therefore, no longer exist in FY 2013), because they meet the definition of a ''subsection (d)'' hospital. SCHs are paid in the interim (prior to cost report settlement) on a claim by claim basis at the amount that is the higher of the payment based on the hospital-specific rate or the IPPS Federal rate based on the standardized amount. At cost report settlement, the fiscal intermediary or A/B MAC determines if the hospital would receive higher aggregate operating IPPS payments using the hospital-specific rate (for all claims) or the Federal rate (for all claims). MDHs are paid the sum of the Federal payment amount plus 75 percent of any amount by which the hospital-specific rate payment exceeds the Federal rate payment amount.

Although MDH status is to expire at the end of FY 2012, the payments reflected on FY 2011 claims for current

MDHs may be based on the hospital-specific rate. As discussed above, we are generally proposing to use historical MedPAR data to determine the base operating DRG payment amounts that would be used to estimate the amount of funding available for value-based incentive payments for the FY 2013 Hospital VBP Program. Consistent with that proposal, for SCHs and hospitals that have MDH status in FY 2012, we are proposing to use MedPAR data to model the reduced base operating DRG payment amount for each claim as if it were paid based on the Federal standardized amount, rather than using the payments information on the claim (that is, regardless of whether a claim was paid under the hospital-specific rate or the Federal rate, the reduced base operating DRG payment amounts for SCHs and current MDHs would be estimated using the Federal rate).

We welcome public comment on these proposals. We also welcome comment on other suggested approaches to most accurately estimate these amounts.

c. Proposed Methodology To Calculate the Value-Based Incentive Payment Adjustment Factor

In accordance with section 1886(o)(6)(C)(i) of the Act, for each eligible hospital that receives a TPS greater than zero with respect to a fiscal year, we are proposing to calculate a value-based incentive payment percentage for that hospital for that fiscal year. In accordance with section 1886(o)(6)(C)(ii) of the Act, the value-based incentive payment percentage that we calculate for the hospital will be based on that hospital's individual TPS, and the total amount of value-based incentive payments to all hospitals in the fiscal year will be equal to the total amount available for value-based incentive payments for the fiscal year, as estimated by the Secretary. We are proposing to define the term ''value-based incentive payment percentage'' in § 412.160 as the percentage of the total base operating DRG payment amount that a hospital has earned back, based on its TPS to that fiscal year. The hospital may earn a value-based incentive payment percentage that is less than, equal to, or more than the applicable percent. The applicable percent that we will use to reduce the base operating DRG payment amount for each FY 2013 discharge is 1.0 percent.

A hospital may earn a value-based incentive payment percentage that is greater than the applicable percent, which would result in that hospital receiving a value-based incentive payment adjustment factor that is greater than one and a higher base operating DRG payment amount for each discharge than it would have received in the absence of the Hospital VBP Program. The proposed calculation of the value-based incentive payment adjustment factor is discussed in further detail below. A hospital may earn a value-based incentive payment percentage that is equal to the applicable percent, which would result in the hospital receiving a value based incentive payment adjustment factor of 1 and the same base operating DRG payment amount that it would have received for each discharge in the absence of the Hospital VBP Program. Alternatively, a hospital may earn a value-based incentive payment percentage that is less than the applicable percent, which would result in the hospital receiving a value-based incentive payment adjustment factor that is less than one and a lower base operating DRG payment amount for each discharge than it would have received in the absence of the Hospital VBP Program.

In order to convert a hospital's TPS into a value-based incentive payment factor that would be applied to each discharge in the applicable fiscal year, we are proposing to use the linear exchange function that we finalized in the Hospital Inpatient VBP Program final rule (76 FR 26534). Under this proposed methodology, we would utilize the following computed amounts:

- The hospital's estimated total annual base-operating DRG amount for all discharges for the applicable fiscal year;
- The applicable percent for the fiscal year (1.0 percent in FY 2013);
- The (linear) exchange function slope; and
- The hospital's TPS.

The following six (6) steps illustrate our proposed methodology:

Step 1: Estimate the hospital's total annual base-operating DRG amount. First, we would estimate each hospital's total annual base operating DRG amount for all discharges in the applicable fiscal year. As we discussed above, we are proposing to estimate this amount using Medicare inpatient claims data taken directly from the most recently available MedPAR files.

Step 2: Calculate the total annual estimated base operating DRG payment reduction amount across all eligible hospitals. Second, we are proposing to estimate the total base operating DRG reduction amount across all eligible hospitals (which is the total amount available for value-based incentive payments) according to the following two steps:

Step 2a: Repeat Step 1 for all eligible hospitals, and multiply the *estimated total amount for each hospital* by the applicable percent. For FY 2013, the applicable percent is 1.0 percent; then

Step 2b: Add together the amount for each hospital calculated under Step 2a. This sum is the total amount available for value-based incentive payments, and the numerator of the linear exchange function slope that is calculated in Step 3 below.

Step 3: Calculate the linear exchange function slope. Third, we would calculate the linear exchange function slope. As noted above, we finalized the use of a linear exchange function for the purpose of converting a hospital's TPS into a value-based incentive payment percentage. We would calculate the linear exchange function slope using the following steps:

Step 3a: Convert the TPS for each hospital into a decimal by dividing it by 100. The TPS may range from zero to 100. In this step, we express it as a number between zero and 1.

Step 3b: Multiply each hospital's estimated total base-operating DRG payment reduction amount for the applicable fiscal year (from Step 2a above) by the hospital's TPS (decimal between zero and one from Step 3a above).

Step 3c: Add together the numbers computed in Step 3b above. This sum represents the denominator of the linear exchange function slope that is calculated in Step 3d below.

Step 3d: The exchange function slope equals the sum computed in Step 2b above divided by the sum computed in Step 3c above.

Step 4: For each hospital, calculate the hospital's value-based incentive payment percentage for the fiscal year. We are proposing to use the exchange function slope (from Step 3) and the hospital's TPS to calculate the hospital's value-based incentive payment percentage that it earned as a result of its performance under the Hospital Inpatient VBP Program for the fiscal year. We could calculate the value-based incentive payment percentage by multiplying the applicable percent by the amount computed for the hospital in Step 3a and the exchange function slope as computed in Step 3d above. This is the mathematical approach to locating the place along the linear exchange function where a given hospital's TPS score would be located and identifying the corresponding value-based incentive payment percentage. As we note above, the value-based payment percentage could be greater than, equal to, or less

than the applicable percent that is applied to reduce the base operating DRG payment amount for each discharge.

Step 5: Compute the net percentage change in the hospital's base-operating DRG payment amount for each discharge. Fifth, we are proposing to calculate the net percentage change to the hospital's base operating DRG payment amount for each discharge in the applicable fiscal year. We would calculate the net change as an intermediate step, in order to determine the value-based incentive payment adjustment factor described in Step 6, below. The net percentage change in the hospital's base operating DRG payment amount for each discharge would be the difference between the applicable percent and the value-based incentive payment percentage. We would calculate this net change for each hospital by subtracting the applicable percent used in Step 2a (1 percent for FY 2013) from the value based incentive payment percentage computed for the hospital in Step 4. This net change in the base-operating DRG payment amount would be expressed as a percentage and could be positive, zero, or negative, depending on the hospital's TPS and the exchange function slope.

Step 6: To calculate this factor, we would convert the hospital's individual net percentage change in its base-operating DRG payment amount, from Step 5, from a percentage into a number (by removing the percent sign and dividing it by 100) and add it to 1. The 1 would reflect the base operating DRG payment amount that the hospital would have received for a discharge in the absence of the Hospital VBP Program. The result is that a hospital with a positive net percentage change to its total base operating DRG payment amount would have a value-based incentive payment adjustment factor that is greater than one. This means that we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number greater than one.

A hospital with no net percentage change to its total base operating DRG payment amount percentage would have a value-based incentive payment adjustment factor of one. This means that we would multiply its base operating DRG payment amount for each discharge occurring in the applicable fiscal year by 1, and its base-operating DRG payment amount would be equal to what it would have been in the absence of the Hospital VBP Program.

A hospital with a negative net percentage change to its total base-operating DRG payment amount percentage would have a value-based incentive payment adjustment factor that is less than one. This means that we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number less than one.

Example Calculation of the Value-Based Incentive Payment Amount Adjustment: As an example, assume the following information:

- The hospital's estimated total annual base operating DRG payment amount for all discharges in the applicable fiscal year = $1,000,000;
- The applicable percent that is applied to all discharges of eligible hospitals in FY 2013 = 1.0 percent;
- The exchange function slope = 2.0;
- The hospital's TPS = 80.

Under our proposal, we would replicate the six steps to convert a hospital's TPS into a value-based incentive payment adjustment factor as follows:

Step 1: Estimate the hospital's total annual base operating DRG payment amount. We would add together the estimated base-operating DRG payment amount for each FY 2013 discharge. In this example, we assume this total amount would be $1,000,000.

Step 2: Calculate the *total annual estimated* base operating DRG payment reduction amount across all eligible hospitals. Second, we would:

Step 2a: Repeat Step 1 for all eligible hospitals, and multiply the total amount for each hospital by the applicable percent, which is 1.0 percent in this example: $1,000,000 * .01 = $10,000; and

Step 2b: Add together the amount for each hospital calculated in Step 2a above. In this example, we assume this amount is a given. We note that computing this amount requires knowledge of all eligible hospitals' estimated total base operating DRG payment reduction amount.

Step 3: Calculate the linear exchange function slope, which we assume in this example to be 2.0. We note that computing the slope requires knowledge of all eligible hospitals' estimated total base operating DRG payment reduction amount and their TPS to compute the relevant sums that are used in the numerator and denominator of the slope.

Step 4: Calculate the hospital's value-based incentive payment percentage. The hospital's value-based payment percentage would be computed as follows: 0.01 (The applicable percent would be multiplied by 0.80 (the hospital's TPS divided by 100) and 2.0 (the exchange function slope). Mathematically, 0.01 * 0.80 * 2.0 = 0.016, which can be written as 1.60 percent. Therefore, the hospital's value-based incentive payment percentage for the FY 2013 Hospital VBP program would be 1.60 percent ($16,000 in this example).

Step 5: Compute the net percentage change in the hospital's base-operating DRG payment amount for each discharge by subtracting 1.0 percent (the applicable percent) from the value-based incentive payment percentage that the hospital earned based on its TPS.

In this example, the net percentage change would equal 1.60 percent minus 1.00 percent, or 0.60 percent. In this example, the net percentage change is positive and corresponds to a dollar amount of 0.60 percent of the estimated total annual base operating DRG payment amount for the hospital of $1,000,000(0.60 percent * $1,000,000 = $6,000).

Step 6: Compute the value-based payment adjustment factor as equal to the net percentage change calculated in Step 5), expressed as a number, plus one. In this example, the hospital's value-based payment adjustment factor would equal the sum of 0.006 (0.60 percent expressed as a number) plus one.

Therefore, this hospital's value-based payment adjustment factor would equal 1.006, and this factor would be multiplied by the based operating DRG payment amount for each discharge occurring in FY 2013. This hospital had a positive net percentage change to its total base operating DRG payment amount and would have a value-based incentive payment adjustment factor that is greater than one, so we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number greater than one. In this example, the hospital would earn a total value-based incentive payment estimated at $16,000 for all discharges in the fiscal year) that is greater than the 1.0 percent base operating DRG payment reduction amount applied to each discharge in the fiscal year (estimated $10,000 total reduction), which would result in the hospital receiving a higher payment amount for each discharge occurring in FY 2013 than it otherwise would have received, in the absence of the Hospital VBP Program (an estimated $6000 total increase in base operating DRG payments for the fiscal year).

We welcome comments on this proposal.

d. Proposed Timing of the Base Operating DRG Payment Amount Reduction and Value-Based Incentive Payment Amount Adjustment for FY 2013 and Future Hospital VBP Program Years

The applicable percent reduction and the value-based incentive payment adjustments are distinct adjustments which we are required to make to base operating DRG payment amounts for eligible hospitals under the Hospital VBP Program. In this section, we outline our proposals for applying these adjustments to the base-operating DRG payment amounts.

In the Hospital Inpatient VBP Program final rule, for the FY 2013 program, we established that we would incorporate the value-based incentive payment adjustment into our claims processing system in January 2013, and that the adjustment would apply to all FY 2013 discharges, including those that occurred beginning on October 1, 2012 (76 FR 26536). Because of this January 2013 application of the value-based incentive payment adjustment, we are proposing that we would not apply the 1.00 percent applicable reduction to the base operating DRG payment amount for each discharge until we apply the value-based incentive payment adjustment factor. In other words, we would add the value-based incentive payment amount to the hospital's reduced base-operating DRG payment amount for each FY 2013 discharge at the same time that we apply the 1.00 percent reduction to the base operating DRG payment amount. The simultaneous application of the 1.00 percent reduction to the base-operating DRG payment amounts and the value-based incentive payment amount (if applicable, based on the hospital's TPS) would prevent hospitals from receiving a 1.00 percent reduction to their base operating DRG payment amounts before they receive their value-based incentive payment amount adjustment. Accordingly, under our proposal, beginning in January 2013, a hospital would receive a base operating DRG payment amount for each discharge occurring in FY 2013 that is the net result of the application of the 1.00 percent reduction and the application of the hospital's individual value-based incentive payment amount adjustment.

In FY 2014 and future years of the Hospital VBP Program, we are proposing to apply both the applicable percent reduction and the value-based incentive payment amount adjustment to the base operating DRG payment amount for a discharge during the regular claim payment process, beginning in October of each fiscal year. These adjustments would be made simultaneously with respect to each discharge.

We invite public comment on this proposal.

e. Proposed Process for Reducing the Base Operating DRG Payment Amount and Applying the Value-Based Incentive Payment Amount Adjustment for FY 2013

In developing our proposal for FY 2013, we have considered two different methodologies for applying the 1.00 percent reduction to the base operating DRG payment amount for each discharge, and for applying the value-based incentive payment adjustment to the reduced base operating DRG payment amount: (1) Reprocessing the claims submitted prior to January 2013, which is when we expect to incorporate the value-based incentive payment adjustments into our claims processing system; and (2) modifying the exchange function slope, in such a way as to redistribute the value-based incentive payment adjustments for discharges occurring prior to incorporating the adjustments into our claims processing system. Neither approach would require hospitals to resubmit claims.

We are proposing to reprocess the claims submitted by hospitals for discharges occurring between October 1, 2012 and such time as the value-based incentive payment adjustments are incorporated into the claims processing system. We believe that this approach is the most straightforward way to address the January implementation of FY 2013 value-based incentive payment adjustments. For the second methodology we considered, we would need to modify the exchange function slope, because adjustments would not have been made beginning on October 1, 2012, the start of FY 2013. As described in section VIII.C.5.c. of this preamble, calculation of the exchange function slope is based on the hospital TPS and the amount available for value-based incentive payments. The total amount available to make value based incentive payments to eligible hospitals is equal to the total of their base-operating DRG payment reduction amounts, as estimated by the Secretary, according to section 1886(o)(6)(C)(ii)(I) of the Act.

Under this approach, we would account for this delay in implementation of applicable percent reductions and value-based incentive payment adjustments by modifying the computed exchange function slope so that we could use it to calculate a value-based incentive payment adjustment for each hospital that would distribute the total amount available for value based incentive payments between January and September 30, 2013. We would modify the exchange function to accomplish this by multiplying its slope by the following fraction: The total number of days in the fiscal year/(divided by) the number of days between the date we incorporate adjustments and the end of the fiscal year. For example, if the date the value-based adjustment is incorporated into the system is January 15, then the number of days between January 15, 2013 and September 30, 2013 is 258. Therefore, we would multiply the exchange function slope by 365/258, in order to redistribute the value-based incentive payment adjustments that occur on or after January 15, 2013 in such a manner that they also account for discharges occurring between October 1, 2012 and January 15, 2013. For purpose of calculating the exchange function slope modification, we would assume that hospitals' base operating DRG payments are constant throughout the fiscal year (that is, DRG payments are not concentrated in the beginning or the end of the year, for example).

We believe that this alternative approach could cause confusion regarding payment amounts for discharges that occur between the beginning of the fiscal year and the implementation of the value-based incentive payment adjustments but are not billed until after the implementation of the value-based incentive payment adjustments. Those claims would be paid as though the applicable percent reduction and the value-based incentive payment adjustments were not in effect, because they would be based on date of discharge.

We invite public comment on our proposed approach to reprocess hospital inpatient claims that are billed between October 1, 2012 and such time as we are able to incorporate the value-based incentive payment adjustments into our claims processing system in January 2013. We recognize that hospitals would be responsible for maintaining their own internal accounting systems in order to accommodate the reprocessing of these claims in January 2013; therefore, we are also inviting public comment on the alternative approach described above of modifying the exchange function slope to redistribute the value-based incentive payment adjustments, or any other approaches which might minimize the administrative burden imposed upon hospitals.

6. Proposed Review and Corrections Processes

a. Background

Section 1886(o)(10)(A)(i) of the Act requires that the Secretary make information available to the public regarding individual hospital performance in the Hospital VBP Program, including: (1) The performance of the hospital on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's TPS. To comply with this requirement, we stated in the Hospital Inpatient VBP Program final rule that we intended to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, and SCIP), each hospital's domain-specific score, and each hospital's TPS on the *Hospital Compare* Web site (76 FR 26534 through 26536).

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to each hospital under section 1886(o)(10)(A)(i) of the Act prior to such information being made public. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74545), we finalized procedures that will enable hospitals to review and correct both the underlying data and measure rates for the clinical process of care measures and HCAHPS dimensions under the Hospital VBP Program (76 FR 74545 through 74547).

In this proposed rule, we are making additional proposals that will enable hospitals to review and correct their claims-based measure rates, as well as their condition-specific scores, domain-specific scores, and TPSs.

b. Proposed Review and Corrections Process for Claims-Based Measure Rates

We use claims/administrative data to calculate measure rates for measures that we have adopted for a number of pay for reporting and pay for performance programs, such as the Hospital VBP Program. For claims-based measures used in the Hospital IQR Program, we currently provide hospitals with confidential reports containing the measure rate calculations and accompanying confidential detailed discharge-level information prior to making the rates available to the public. With respect to the claims-based measures we adopt for the Hospital VBP Program, we are proposing to deliver the same type of confidential reports and accompanying confidential detailed discharge-level information for purposes of providing hospitals an opportunity to review and submit corrections for their claims-based measure rates under section 1886(o)(10)(A)(ii) of the Act.

The confidential reports would contain the claims-based measure rate calculations and would be accompanied by additional confidential discharge-level information based on the most recent administrative data available at the time we run the data for purposes of calculating the rates. As we discuss below, we are proposing to create extracts of the data to be used for measure rate calculation purposes approximately 90 days after the last discharge date in the performance period for the measure. Our intent in providing the confidential reports and accompanying discharge-level data to hospitals is twofold: (1) To provide hospitals with an opportunity to review and submit corrections for the measure rates that we will make available to the public; and (2) to facilitate hospitals' quality improvement efforts with respect to the measures. The discharge-level information would contain data derived from claims and administrative data that were used in the calculation of the measure rates. Depending on the measure, this discharge level information might include data elements such as dates of admission, dates of discharge, patient risk factors, primary and secondary diagnoses, procedures, dates of death, dates of service after discharge by the same or other providers/suppliers, and provider/supplier numbers. The confidential reports and accompanying discharge level data would be delivered to each hospital via its secure QualityNet account.

We are proposing to provide hospitals a period of 30-days to review and submit corrections for the claims-based measure rates contained in their confidential reports. This 30-day period would begin the day hospitals' confidential reports and accompanying discharge-level data are posted to QualityNet. These measure rates will be used for performance scoring, value-based incentive payment amount calculations, and public reporting for the Hospital VBP Program. Based on our previous experience with public reporting of measures under the Hospital IQR Program, including the 30-day risk standardized mortality rates and the AHRQ Patient Safety Indicators, we believe this 30-day period will allow enough time for hospitals to review their data and notify us of suspected errors in the measure rate calculations, and for us to incorporate appropriate corrections to the calculations. During the review and correction period, hospitals should notify us of suspected errors using the technical assistance contact information provided in their confidential reports.

The review and correction process we are proposing to adopt for the claims-based measure rates would not allow hospitals to submit corrections related to the underlying claims data we used to calculate the measure rates, or allow hospitals to add new claims to the performance period data set that we ran to calculate the rates. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the calculations. For purposes of this program, we would calculate the claims-based measures using claims and corrections to claims submitted by hospitals that were incorporated into our claims database during the approximately 90 day period following the last date of discharge to be included in the measure calculation.

We recognize that under our current timely claims filing policy, hospitals have up to one year from the date of discharge to submit a claim. However, in using claims and other administrative data to calculate measure rates for the Hospital VBP Program, we are proposing to create data extracts using claims information as it exists in our Common Working File (CWF) approximately 90 days after the last discharge date in the performance period for the measures. For example, if the last discharge date in the performance period for a measure is June 30, 2011, we would create the data extraction on or about September 30, 2011 and use that data to calculate the measure rate for that performance period. Hospitals would then receive the measure rate in their confidential reports and accompanying data, and they would have an opportunity to review and submit corrections to that rate. As we stated above, hospitals would not be able to submit corrections to the underlying data that we extracted on or about September 30, 2011, and would also not be able to add claims to the data set. We would consider the underlying claims and administrative data to be complete for purposes of the Hospital VBP Program claims-based measure calculations at the conclusion of the approximately 90 day period following the last date of discharge used in the performance period.

We considered a number of factors in determining that an approximately 90 day ''run-out'' period is appropriate for purposes of calculating the claims-based measure rates. First, we seek to provide

timely quality data to hospitals for the purpose of quality improvement, and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals as close in time to the applicable performance period as possible. Finally, we seek to have as complete a data set as possible, recognizing that hospitals have up to one year from the date of discharge to submit a claim under our timely claims filing policy.

After we run the data and create the data extract for purposes of calculating the measure rate for a claims-based measure, it takes several months to incorporate other data needed to complete the rate calculation (particularly in the case of a risk-adjusted and/or episode based measure). We then need to generate and check the rate calculations, as well as program, populate, and deliver the confidential reports and accompanying data to hospitals. We are also aware that hospitals would like to receive performance information under the Hospital VBP Program as close in time to the performance period as possible. If we were to wait to run the data for purposes of calculating the claims-based measure rates until at least 12 months after the last discharge date in the performance period, we would not, for operational reasons, be able to provide the measure rates to hospitals 18 to 24 months after the performance period ended. We believe that this would create an unacceptably long delay both for hospitals that are interested in receiving timely measure rate calculations for their own quality improvement efforts, and for us to (1) calculate TPSs for a program year and (2) publicly report hospital performance on the *Hospital Compare* Web site. Therefore, we are proposing to extract the data needed to calculate a claims-based measure approximately 90 days after the last discharge date for the measure's performance period so that we can best balance our need to provide timely program information to hospitals against the need to calculate the claims-based measures using as complete as a data set as possible.

During the 30-day review and correction period, hospitals should notify us of suspected errors in our calculation of the measure rates using the technical support contacts provided in the hospital's confidential report. We would investigate the validity of each submitted correction and notify hospitals of the results. Should we confirm that we made an error in calculating one or more claims-based measure rates included in a hospital's confidential report, we would correct the calculation(s) and issue a new confidential report to the hospital. We are proposing that once the 30-day review and corrections period has concluded, we would not accept any additional corrections submitted by a hospital.

We invite public comment on the proposed review and correction process for claims-based measure rates to be used in the Hospital VBP Program.

c. Proposed Review and Correction Process for Condition-Specific Scores, Domain-Specific Scores and TPSs

We are proposing to adopt a review and corrections process that will enable hospitals to review and submit corrections with respect to their performance on each condition (the condition-specific score), their performance on each domain (the domain-specific score) and their TPSs. Under this proposed process, we would provide each hospital with a TPS Report (this would be a different report than the hospital confidential report and accompanying data described above, and the reports described in previous rules that will enable hospitals to review and correct their chart-abstracted and HCAHPS measure data). A hospital would have 30 days from the date we post the report on its QualityNet account to review the TPS Report and submit any necessary corrections to us via QualityNet. This proposed requirement will enable us to evaluate corrections requests and provide decisions on those requests in a timely manner. As discussed further below, we are also proposing that the submission of a correction through this process be a prerequisite to a hospital being able to submit an appeal of the calculation of its performance assessment with respect to the performance standards and/or its TPS under section 1886(o)(11)(A) of the Act.

Hospitals would not be able to use this proposed review and correction process to ask us to reconsider a hospital's eligibility under section 1886(o)(1)(C) of the Act to participate in the Hospital VBP Program for a fiscal year. However, we seek public comment on whether our determination regarding a hospital's eligibility should be subject to correction.

We believe that this proposed review and corrections process will ensure that hospitals are able to fully and fairly review their condition-specific scores, domain-specific scores, and TPS. We are inviting public comment on this proposal. We note that we anticipate posting FY 2013 hospital performance information on *Hospital Compare* in April 2013. We are proposing to codify this for posting hospital-specific information in our regulations at § 412.163.

We view the review and corrections process as separate and distinct from the appeals process. Each process is aimed at allowing hospitals to seek certain reconsiderations from CMS. The review and corrections process is aimed at correcting data that will be made public on the *Hospital Compare* Web site, while the appeals process allows hospitals to seek reconsideration for errors that may have been introduced during the TPS calculation that may affect hospitals' payments.

7. Proposed Appeal Process Under the Hospital VBP Program

a. Background

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A) of the Act) and the hospital performance score (section 1886(o)(5) of the Act).

Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act; (3) the establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act; (4) the measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act; (5) the methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores; or, (6) the validation methodology specified in section 1886(b)(3)(B)(viii)(XI) of the Act.

b. Proposed Appeal Process

We solicited public comments on the general structure and procedures we should consider when developing an appeals process for the Hospital VBP Program in the Hospital Inpatient VBP Program proposed rule (76 FR 2484). We took these comments into consideration

when we developed the proposed appeals process that appears below. We are proposing to implement an administrative appeals process that provides hospitals with the opportunity to appeal the calculation of their performance assessment with respect to the performance standards, as well as their TPS.

We are proposing to codify this proposed appeals process in our regulations at § 412.167.

Under our proposed appeals process, if a hospital is seeking to appeal a calculation of the TPS, measure/dimension score, condition-specific score, domain specific score, or measure rate/data for which the hospital could have submitted a correction during the review and correction process we have both previously finalized (with respect to chart-abstracted and HCAHPS data) and are proposing to adopt in this proposed rule, we would require that the hospital first submit a correction to that calculation, and receive an adverse determination from us, as part of that process before the hospital could challenge it under the appeals process. We are proposing to adopt this requirement because we believe that we will be able to resolve many hospital claims through the review and corrections process, and thus eliminate the need for an appeal. To the extent that a hospital seeks to appeal a calculation that was the subject of a correction request, we are proposing that the deadline for the hospital to submit an appeal under section 1886(o)(11)(A) of the Act would be 30 days from the date the we informed the hospital through QualityNet of our decision on the correction request. For any other appeals requests, we are proposing that hospitals have up to 30 days after the conclusion of the review and corrections period specified above to submit an appeal. We seek public comment on the appropriateness of this proposed appeals timeline and whether we should consider any other possible deadlines.

We are proposing that all appeals be submitted through QualityNet and that they contain the following information:

- Hospital's CMS Certification Number (CCN)
- Hospital Name
- Hospital's basis for requesting an appeal. This must identify the hospital's specific reason(s) for appealing the hospital's TPS or performance assessment with respect to the performance standards.
- CEO contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).
- QualityNet System Administrator contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

Consistent with sections 1886(o)(11)(A) and (B) of the Act, we are proposing that hospitals would be able to submit an appeal on the following issues:

- CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;
- Whether the achievement/improvement points were calculated correctly;
- Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;
- Whether CMS correctly calculated the domain scores, including the normalization calculation;
- Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;
- Whether CMS calculated the HCAHPS consistency points correctly;
- Whether the correct domain scores were used to calculate the TPS;
- Whether each domain was weighted properly;
- Whether the weighted domain scores were properly summed to arrive at the TPS; and,
- Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

We invite public comment on this proposed administrative appeal process.

8. Proposed Measures for the FY 2015 Hospital VBP Program

a. Relationship Between the National Strategy and the Hospital VBP Program

Section 399HH of the Public Health Service Act, as added and amended by sections 3011 and 10302 of the Affordable Care Act, requires the Secretary to establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health. The Secretary submitted the ''National Strategy for Quality Improvement in Health Care'' on March 21, 2011. The strategy is available at: *http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.*

We believe we can incorporate the goals of the National Quality Strategy into our policies under the Hospital VBP Program. We view the strategy as an important driver in revamping how Medicare services are paid for, moving increasingly towards rewarding hospitals that deliver better outcomes in health and health care at lower cost to the beneficiaries and communities they serve. Over time, the strategy is also helping us align the goals for quality measurement and improvement in hospitals with those of other providers and suppliers in the health system, promoting shared accountability across care settings for beneficiary care and quality improvement.

We believe that, given the availability of endorsed measures and the need to balance the number and scope of the measures against the burden on participating hospitals, as well as ensuring that the Hospital VBP Program's measure set reflects our quality improvement priorities, the Hospital VBP Program measures should as fully as possible reflect the six measurement domains that arise from the National Quality Strategy's six priorities: Clinical Care; Person- and Caregiver-Centered Experience and Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/Population Health. We believe that measure sets should generally rely on a mix of standards, outcome, process of care measures, and patient-reported measures including measures of care transitions, patient experience, and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible. We took all of these factors into consideration when developing our measure proposals for the FY 2015 Hospital VBP Program.

In addition, we believe that measure sets should evolve to include a focused set of measures that reflect the most important areas of service and quality improvement for hospitals as well as a core set of measure concepts that align quality improvement objectives across all provider types and settings.

b. Proposed FY 2015 Measures

In the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497), we adopted a policy under which we would examine whether any clinical process of care measures that were otherwise eligible for inclusion in a Hospital VBP Program measure set were topped-out, and thus, should be excluded because measuring hospital performance on a topped-out measure would have no meaningful effect on a hospital's TPS. Our methodology for evaluating whether a measure is topped-out focuses on two criteria: (1) National

measure data show statistically indistinguishable performance levels at the 75th and 90th percentiles, and (2) National measure data show a truncated coefficient of variation (TCV) less than 0.10.

We analyzed the clinical process of care measures that we believe are eligible for the FY 2015 Hospital VBP Program based on their prior inclusion in the Hospital IQR Program and posting on *Hospital Compare* for ''topped out'' status, and concluded that one of the candidate measures for the FY 2015 Program—SCIP–Inf-10: Surgery Patients with Perioperative Temperature Management—is now ''topped-out.'' Therefore, we are not proposing to include this measure in the FY 2015 Hospital VBP Program.

We welcome public comments on whether any other existing Hospital VBP measures may be ''topped out'' and should therefore be considered for removal from the proposed measure set. We also note that we do not believe it is appropriate at this time to test or re-test proposed outcome measures for ''topped-out'' status because such measures allow CMS to reward hospitals for high-quality outcomes, which is a central aim of quality improvement efforts in the health care system. We further believe that these measures are critical to providing patients with better care and believe it is important to hold hospitals accountable for the clinical outcomes captured by these measures. We invite public comments on this policy, including whether we should examine the proposed outcomes measure set for ''topped-out'' status at this time.

For the FY 2015 Hospital VBP Program, we are proposing to retain 12 of the 13 clinical process of care measures that we have adopted for the FY 2014 program. We are proposing to remove SCIP–VTE–1 from the FY 2015 measure set because this measure is very similar to another measure we have adopted for the program (SCIP–VTE–2) but, in our view, is not as closely linked to better surgical outcomes because it assesses the ordering of VTE prophylaxis, as opposed to the patient's actual receipt of such prophylaxis within 24 hours of surgery. We also note that, during a recent maintenance review of SCIP–VTE–1, the NQF concluded that it would no longer endorse this measure, and we are proposing in this proposed rule to remove the measure from the Hospital IQR Program beginning with the FY 2015 payment determination. Therefore, we are also proposing to retire SCIP–VTE–1 from the Hospital VBP Program measure set beginning with the FY 2015 program. We note that in the future, we anticipate proposing to adopt surgical outcome measures, including one or more measures that assess complications arising from VTE prophylaxis medications, first into the Hospital IQR Program and then into the Hospital VBP Program.

We are proposing to adopt one additional clinical process of care measure—AMI–10: Statin Prescribed at Discharge. This measure has been specified under the Hospital IQR Program for the FY 2013 payment determination (75 FR 50200). AMI–10 measure data were posted on the *Hospital Compare* Web site on January 26, 2012, so as discussed further below, we are proposing a 9-month performance period for this measure for FY 2015. We intend to align the performance period for AMI–10 with the other clinical process measures' performance period in future years. The measure is NQF-endorsed (#0639) and we did not find it to be ''topped-out'' when we examined the list of candidate measures as described above. We also note that current American College of Cardiology (ACC)/American Heart Association (AHA) guidelines place a strong emphasis on the initiation or maintenance of statin drugs for patients hospitalized with AMI, particularly those with LDL-cholesterol levels at or above 100 mg/dL. We therefore believe that this measure is appropriate for use in the Hospital VBP Program.

For the Patient Experience of Care domain, we are proposing to retain the eight dimensions of the HCAHPS survey that we adopted for the FY 2013 and FY 2014 Hospital VBP Program. We believe that the 8 HCAHPS dimensions finalized for the FY 2013 and FY 2014 Hospital VBP Programs are well-understood by hospitals and the public and capture important aspects of the patient's experience in the acute care environment.

For the Outcome domain, we are proposing to retain the three 30-day mortality measures that we finalized for the FY 2014 Hospital VBP Program. As described above, we continue to believe that these measures are important to quality improvement efforts because outcomes measures allow us to reward hospitals for high-quality outcomes, which is a central aim of quality improvement efforts in the health care system. We further believe that these measures are critical to providing patients with better care and believe it is important to hold hospitals accountable for the clinical outcomes captured by these measures. We also are proposing to adopt two additional outcomes measures—PSI–90, the AHRQ PSI composite measure, and the CLABSI: Central Line-Associated Blood Stream Infection measure—for the Outcome domain.

We initially adopted the CLABSI measure for the FY 2013 Hospital IQR Program in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50200 through 50202) and refer readers to that rule for further discussion of the measure. CLABSI is an HAI measure that assesses the rate of laboratory-confirmed cases of bloodstream infection or clinical sepsis among ICU patients. This measure was first NQF-endorsed in 2004, and adopted by the HQA in 2007. The measure can be stratified by the type of ICU and is aggregated to the hospital level by the NHSN. We first posted hospital performance on this measure on *Hospital Compare* on January 26, 2012.

We believe that adoption of the CLABSI measure for the Hospital VBP Program is consistent with the intention captured in the Hospital VBP Program's statutory requirement that we consider measures of HAIs for the FY 2013 Hospital VBP Program's measure set.

We initially adopted the AHRQ PSI composite measure (PSI–90) for the FY 2010 payment determination in the FY 2009 IPPS/LTCH PPS final rule (73 FR 48602 through 48603) and refer readers to that rule for further discussion of that measure. PSI–90 is a composite measure of patient safety indicators developed and maintained by AHRQ and measure data were posted on *Hospital Compare* on October 14, 2011. We believe that its use in the Hospital VBP Program is appropriate in order to encourage hospitals to take all possible steps to avoid threats to patient safety that may occur in the acute care environment.

For the Efficiency domain, we are proposing to adopt one new measure: the Medicare Spending per Beneficiary measure. The proposed measure is inclusive of all Part A and Part B payments from 3 days prior to a subsection (d) hospital admission through 30 days post discharge with certain exclusions. It is risk adjusted for age and severity of illness, and the included payments are standardized to remove differences attributable to geographic payment adjustments and other payment factors. We anticipate submitting the proposed measure to the NQF for endorsement in the near future.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627) for the measure's specifications. Additional information on the measure, including a detailed specification document can be found at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%*

2FPage%2FQnetTier3&cid=1228772053996. This measure has been specified under the Hospital IQR Program, and we anticipate publicly posting hospital performance on the measure on the *Hospital Compare* Web site in mid to late April 2012. As discussed further below, we are proposing that the performance period for this measure for the FY 2015 Hospital VBP Program begin on May 1, 2013, which will be more than one year after the performance data has been publicly posted. Further, section 1886(o)(2)(B)(ii) of the Act requires us to ensure that measures selected for the Hospital VBP Program include measures of efficiency, including measures of Medicare spending per beneficiary, for FY 2014 or a subsequent fiscal year. We believe that this proposed measure fulfills that requirement.

The proposed FY 2015 Hospital VBP Program measures appear below:

PROPOSED QUALITY MEASURES FOR FY 2015 HOSPITAL VBP PROGRAM

Measure ID	Description
Clinical Process of Care Measures	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
AMI–10	Statin Prescribed at Discharge.
HF–1	Discharge Instructions.
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
SCIP–Inf–9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2.
SCIP–Card–2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience Measures	
HCAHPS *	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.
Outcome Measures	
AHRQ PSI composite	Complication/patient safety for selected indicators (composite).
CLABSI	Central Line-Associated Blood Stream Infection.
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate.
MORT–30–HF	Heart Failure (HF) 30-day mortality rate.
MORT–30–PN	Pneumonia (PN) 30-day mortality rate.
Efficiency Measures	
MSPB–1	Medicare spending per beneficiary.

* Proposed dimensions of the HCAHPS survey for use in the FY 2015 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions of the HCAHPS survey that have been finalized for prior Hospital VBP program years.

We invite public comment on the proposed measure set for the FY 2015 Hospital VBP Program.

c. Proposed General Process for Hospital VBP Program Measure Adoption for Future Program Years

In order to facilitate measure adoption for the Hospital VBP Program for future years, as well as further align the Hospital VBP Program with the Hospital IQR Program, we are proposing to re-adopt measures from the prior program year for each successive program year, unless proposed and finalized otherwise (for example, because one or more of the clinical process of care measures is topped-out). We intend to continue monitoring Hospital VBP measures for topped-out status and will propose topped-out measures' removal from the program as appropriate in future rulemaking. We will therefore generally re-adopt the prior Program year's measure set unless we propose to add or remove measures through rulemaking and in response to public comments. However, under this policy, once measures are finalized, we would not separately re-propose them for each program year. We invite public comments on this proposal.

9. Proposed Measures and Domains for the FY 2016 Hospital VBP Program

a. Proposed FY 2016 Measures

We are proposing to retain the three 30-day mortality measures that were finalized for the FY 2014 Hospital VBP Program, and which we are proposing to retain for the FY 2015 Hospital VBP Program, for the FY 2016 Hospital VBP Program. We also are proposing to retain PSI–90, which is the AHRQ PSI composite measure that we are proposing to adopt for the FY 2015 Hospital VBP Program, for the FY 2016 program. By proposing to adopt these measures now, we believe we will be able to adopt a longer performance period and collect more data for performance scoring than would be possible if we waited to make this proposal until the FY 2014 IPPS/LTCH PPS proposed rule. We are also proposing to adopt these measures at this time because we recognize that under section 1886(o)(3)(C) of the Act, we must establish and announce performance standards not later than 60 days prior to the beginning of the

performance period for the fiscal year involved. Accordingly, we are proposing that the performance period for these measures would begin October 1, 2012, for purposes of the FY 2016 Hospital VBP Program. If we finalize our proposal above to automatically re-adopt measures from year to year, then the other proposed FY 2015 measures would become part of the FY 2016 measure set unless we proposed otherwise in future rulemaking. We also anticipate adopting additional measures for the FY 2016 Hospital VBP Program in future rulemaking.

The proposed FY 2016 Hospital VBP Program 30-day mortality measures and AHRQ PSI composite measure are shown below:

PROPOSED OUTCOME MEASURES FOR FY 2016 HOSPITAL VBP PROGRAM

Measure ID	Description
AHRQ PSI composite	Complication/patient safety for selected indicators (composite).
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate.
MORT–30–HF	Heart Failure (HF) 30-day mortality rate.
MORT–30–PN	Pneumonia (PN) 30-day mortality rate.

We are not proposing to adopt the CLABSI measure for the FY 2016 Hospital VBP Program at this time, but may propose it in future rulemaking.

We invite public comment on these proposals.

b. Proposed Quality Measure Domains for the FY 2016 Hospital VBP Program

Currently, measure domains are defined by the measure type rather than by measure function. At the time of the Hospital VBP Program's development, we believed this type of measure classification, which was included in the 2007 Report to Congress, was appropriate for the program based on its clarity and simplicity compared to alternative scoring models. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26513 through 26514) for further discussion of our decision to finalize the Three-Domain Performance Scoring Model for the Hospital VBP Program with appropriate modifications for additional domains as necessary. The FY 2014 program's domains are clinical process of care, outcomes, and patient experience of care. The FY 2015 Hospital VBP Program's proposed domains are clinical process of care, outcomes, patient experience of care, and efficiency.

We strive to align quality measurement and value-based purchasing efforts with the National Quality Strategy and across programs. Value-based purchasing programs in particular allow us to link the National Quality Strategy with Medicare reimbursements to providers and suppliers on a national scale. Given this objective, as well as our objective to focus quality measurement on the patient-centered outcome of interest to the extent possible, we are proposing to reclassify the Hospital VBP measures into domains based on the six priorities of the National Quality Strategy, beginning with the FY 2016 Hospital VBP Program. We are making this proposal in this proposed rule to ensure that we have ample time to consider all public comments and finalize any policies in advance of the FY 2016 program year.

We are proposing that the following six domains serve as a framework for measurement and TPS calculations for the Hospital VBP Program beginning with the FY 2016 program year: Clinical Care; Person- and Caregiver-Centered Experience and Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/Population Health.

To illustrate how CMS would classify measures into the proposed new domains, we offer the following example using the proposed FY 2015 Hospital VBP measure set:

Proposed FY 2015 measures	Proposed FY 2016 domain	Proposed FY 2015 domain
HF–1 Discharge Instructions	Care Coordination	Clinical Process of Care.
AMI–10 Statin Prescribed at Discharge	Clinical Care	Clinical Process of Care.
AMI–7a Fibrinolytic Agent Received Within 30 Minutes of Hospital Arrival.	Clinical Care	Clinical Process of Care.
AMI–8a Primary PCI Received Within 90 Minutes of Hospital Arrival	Clinical Care	Clinical Process of Care.
Mortality-30–AMI Acute Myocardial Infarction (AMI) 30-day Mortality Rate.	Clinical Care	Outcomes.
Mortality-30–HF Heart Failure (HF) 30-day Mortality Rate	Clinical Care	Outcomes.
Mortality-30–PN Pneumonia (PN) 30–Day Mortality Rate	Clinical Care	Outcomes.
PN–3b Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	Clinical Care	Clinical Process of Care.
PN–6 Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	Clinical Care	Clinical Process of Care.
SCIP Card-2 Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.	Clinical Care	Clinical Process of Care.
SCIP–Inf-01 Prophylactic antibiotic received within 1 hour prior to surgical incision.	Clinical Care	Clinical Process of Care.
SCIP–Inf-02 Prophylactic antibiotic selection for surgical patients	Clinical Care	Clinical Process of Care.
SCIP–Inf-03 Prophylactic antibiotics discontinued with 24 hours after surgery end time.	Clinical Care	Clinical Process of Care.
SCIP–Inf-04 Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.	Clinical Care	Clinical Process of Care.
SCIP–VTE–2 Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	Clinical Care	Clinical Process of Care.
Medicare spending per beneficiary	Efficiency and Cost Reduction	Efficiency.

Proposed FY 2015 measures	Proposed FY 2016 domain	Proposed FY 2015 domain
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems Survey.	Person- and Caregiver-Centered Experience and Outcomes.	Patient Experience of Care.
Central Line-Associated Blood Stream Infection (CLABSI)	Safety	Outcome.
PSI 90 Complication/Patient Safety for Selected Indicators (Composite).	Safety	Outcome.

We acknowledge that some of the measures noted above could appropriately be placed in more than one domain because the quality improvement characteristics they seek to measure, especially for outcome measures, are multifaceted. We believe that the measure classification by domain should reflect the primary measurement objective and the type of quality improvement goal the measure seeks to capture. For example, although a reduction in CLABSIs may reflect improved clinical care, we believe that it better reflects an improvement in patient safety because such infections often cause harm to patients.

We are proposing that the TPS would continue to be determined by aggregating each hospital's scores across all domains. A hospital's score on each domain would also continue to be calculated based on the hospital's score on each measure within the domain, which is based on the higher of its achievement or improvement during the applicable performance period.

We welcome public comment on our proposal to regroup the Hospital VBP Program's quality measures into six domains that better reflect the National Quality Strategy, beginning with the FY 2016 Hospital VBP Program.

We are also soliciting comments on how to properly weight the domains in FY 2016. We believe that domain weighting should primarily balance two factors. First, it should reflect our concept of quality as it relates to the National Quality Strategy and the most critical needs for quality improvement in caring for beneficiaries. Second, it should reflect the relative depth and maturity of measures in each domain. For example, although improvement in the proposed Care Coordination domain is a priority, we would want to take into consideration whether the care coordination measures available for inclusion in that domain in a particular year capture multiple aspects of care coordination. If we did not believe that the measures within a domain captured enough aspects of care, we would consider proposing a relatively lower weight for the domain. We anticipate that the domain weights will evolve over time as the measure set changes.

We also recognize that the current domain weighting system allows us to place higher value on measures closer to the patient-centered outcome of interest by grouping outcome measures into a single domain. In the proposed domain reclassification, the 30-day mortality measures would be grouped with process measures. Although we anticipate that the measure set will evolve over time to be more focused on outcomes, the current measure set continues to emphasize clinical processes. We seek public comment on whether CMS should continue to group all outcome measures in a single domain. In addition, we seek public comment on the implications of and alternatives to the proposed approach of including both clinical process of care measures and outcome measures in the proposed Clinical Care domain under the proposed domain reclassification.

10. Proposed Performance Periods and Baseline Periods for the FY 2015 Hospital VBP Program

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program for a fiscal year that begins and ends prior to the beginning of such fiscal year.

a. Proposed Clinical Process of Care Domain Performance Period and Baseline Period for FY 2015

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74534), for the FY 2014 Hospital VBP Program, we finalized a 9-month (3-quarter) performance period from April 1, 2012 through December 31, 2012 for the clinical process of care domain measures.

As we stated in that final rule with comment period, adopting a 3-quarter performance period for this domain for the FY 2014 Hospital VBP Program would enable us to consider adopting a 12-month performance period for this domain for FY 2015. Therefore, we are proposing to adopt CY 2013 (January 1, 2013 through December 31, 2013) as the performance period for all but one of the clinical process of care domain measures for the FY 2015 program. This proposed performance period for FY 2015 would begin immediately after the end of the FY 2014 performance period and will enable us to begin to make value-based incentive payments to hospitals beginning October 1, 2014. A 12-month performance period would also give us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders. We also note that a 12-month performance period is consistent with the periods used for the Hospital IQR Program.

However, as noted above, AMI–10 measure data were posted on *Hospital Compare* on January 26, 2012. Therefore, we do not believe we can begin a performance period for this measure on January 1, 2013, which would align with the proposed performance period for all other clinical process of care measures. We considered the most appropriate way to include this measure in the FY 2015 Hospital VBP Program and concluded that we should propose a 9-month performance period from April 1, 2013 through December 31, 2013. As we have stated for prior program years, we believe that a 9-month performance period provides sufficiently reliable quality measure data for clinical process of care measures. We intend to align the AMI–10 measure's performance period with all other clinical process measures for future program years. We welcome public comment on this proposal.

As we explained in the Hospital Inpatient VBP Program final rule (76 FR 26511), we believe that baseline data should be used from a comparable prior period for purposes of calculating the performance standards. However, we also strive to balance that belief with our desire to use the most recently-available data in order to calculate performance standards, as we believe that more recent data more closely reflects current performance on measures. Therefore, we are proposing to adopt CY 2011 (January 1, 2011 through December 31, 2011) as the baseline period for all but one of the Clinical Process of Care domain measures for the FY 2015 Hospital VBP Program. As noted above, we are proposing to adopt a 9-month performance period for the AMI–10 measure. In accordance with our preference for adopting a comparable prior period for purposes of calculating the performance standards, we are proposing to adopt a 9-month baseline period of April 1, 2011 through

December 31, 2011 for the AMI–10 measure.

We welcome public comment on these proposals.

b. Proposed Patient Experience of Care Domain Performance Period and Baseline Period for FY 2015

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74534), for the FY 2014 Hospital VBP Program, we finalized a 9-month (3-quarter) performance period from April 1, 2012 through December 31, 2012 for the Patient Experience of Care domain measure.

As we stated in that final rule with comment period, adopting a 3-quarter performance period for this domain for the FY 2014 Hospital VBP Program would enable us to consider adopting a 12-month performance period for this domain for FY 2015. Consistent with our goal of adopting a full 12-month period for this domain in order to collect a larger amount of HCAHPS survey data compared to a 9-month period, we are proposing to adopt CY 2013 (January 1, 2013 through December 31, 2013) as the performance period for the Patient Experience of Care domain measure for the FY 2015 program. This proposed performance period for FY 2015 would begin immediately after the end of the FY 2014 performance period and would enable us to begin making value-based incentive payments to hospitals beginning on October 1, 2014. We also note that a 12-month performance period is consistent with the periods used for the Hospital IQR Program.

As we explained in the Hospital Inpatient VBP Program final rule (76 FR 26511), we believe that baseline data should be used from a comparable prior period for purposes of calculating the performance standards. Therefore, we are proposing to adopt CY 2011 (January 1, 2011 through December 31, 2011) as the baseline period for the Patient Experience of Care domain measure for the FY 2015 program.

We welcome public comment on these proposals.

c. Proposed Efficiency Domain Measure Performance Period and Baseline Period for FY 2015

We plan to post performance data for the Medicare spending per beneficiary measure on *Hospital Compare* in April 2012. We have therefore concluded that the earliest we may begin a performance period for FY 2015 is one year from the date on which the data was posted. We are proposing an end date of December 31, 2013 for this measure's performance period. This end date is consistent with the end dates proposed for the Clinical Process of Care domain and for the HCAHPS measure in the Patient Experience of Care domain.

In the interest of maintaining consistency across domains, to the extent possible, and in order to ensure that data have been posted for at least 1 year prior to the beginning of the measure performance period, we are proposing to adopt an 8-month performance period (May 1, 2013 through December 31, 2013) for the Medicare spending per beneficiary measure for the FY 2015 Hospital VBP Program. We believe this proposed performance period enables us to collect as much measure data as possible and the time necessary to process claims and incorporate measure data into Hospital VBP Program scores. We are further proposing to adopt a corresponding prior period (May 1, 2011 through December 31, 2011) as the baseline period for purposes of calculating the performance standards. This proposed baseline period would be consistent with the baseline period proposed for other Hospital VBP Program measures in that it precedes the performance period by two years.

We welcome public comment on the proposed FY 2015 performance and baseline period for the Medicare spending per beneficiary measure.

d. Proposed Outcome Domain Performance Periods for FY 2015

(1) Mortality Measures

In the Hospital Inpatient VBP Program final rule (76 FR 26495), we finalized a 12-month performance period (July 1, 2011–June 30, 2012) for the Outcome domain for the FY 2014 Hospital VBP Program. We also finalized a comparable prior period as the baseline period (July 1, 2009 through June 30, 2010) for purposes of calculating improvement points as well as the performance standards.

Due to the lengthy time needed for us to compile claims-based measure data at the individual hospital level and calculate the measure rates and scores (discussed more fully in section VIII.C.6.b. of this preamble in the context of our review and corrections proposal for claims-based measures), we must conclude the performance period for claims-based measures for FY 2015 by June 30, 2013.

We are concerned about the difficulty that varied performance periods impose on participating hospitals. While we believe the public recognizes the need for different performance periods due to varied measure types and collection methods, we strive to propose performance periods that are as consistent as possible from one program year to the next. We believe this consistency is important for all hospitals that are working to improve the quality of care they provide to Medicare beneficiaries and to the entirety of the patient population. However, we are also aware that the Hospital VBP statute requires that we establish and announce performance standards for Hospital VBP measures at least 60 days in advance of the performance period. Because we are proposing to adopt these measures for FY 2015 in this proposed rule, which will not be effective until 60 days after it is finalized, we do not believe we can propose a performance period for these measures beginning earlier than October 1, 2012.

We note that this proposed performance period is less than 12 months, which may raise seasonality concerns with regard to these measures. We note further that we examined the independent analysis of these measures' reliability provided by Mathematica Policy Research, entitled, ''Reporting Period and Reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised,'' which is available on our Web site (*http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf*), and which concluded that the measures may not achieve total reliability for all hospitals for reporting periods as short as 6 months. However, we believe that holding all hospitals accountable using the same period will fairly alleviate those concerns, particularly because these measures are risk-adjusted using a methodology that does not penalize hospitals for poor performance on the measure without a relatively larger sample size. As described further below, while we are concerned about these measures' reliability when adopting a performance period of less than 12 months, we believe that increasing the required minimum number of cases will assure sufficient reliability for these measures for value-based purchasing. Based on this analysis, as well as our objective to include outcome measures in the Hospital VBP Program, we believe that the proposed 9-month performance period for these measures will produce sufficiently reliable results for hospitals.

Therefore, we are proposing to adopt a 9-month performance period for the three 30-day mortality measures for FY 2015 from October 1, 2012 through June 30, 2013. We further are proposing a comparable baseline period from October 1, 2010 through June 30, 2011.

We welcome public comment on our proposal to adopt a performance period for the proposed FY 2015 mortality measures that runs from October 1, 2012 through June 30, 2013, and a baseline period that runs from October 1, 2010, through June 30, 2011.

(2) Proposed AHRQ PSI Composite Measure

We posted hospital performance data on the AHRQ PSI composite measure on *Hospital Compare* on October 14, 2011. Based on that posting date, we believe the earliest we could begin a performance period for FY 2015 is October 14, 2012. As discussed above, we must conclude the performance period for claims-based measures by June 30, 2013 in order to allow sufficient time to calculate the measure rates and scores.

Therefore, we are proposing to adopt a nearly 9-month performance period (October 15, 2012 through June 30, 2013) for the AHRQ PSI composite measure for FY 2015. We believe that this performance period will provide us with sufficiently reliable data on which to base hospitals' scores. We further are proposing to adopt a comparable prior period from October 15, 2010 through June 30, 2011 as the baseline period for purposes of calculating the performance standards.

While we would prefer to adopt a performance period longer than nearly 9-months in order to provide the most reliable measure data possible, we believe that the proposed period enables us to ensure that this measure, which assesses hospital performance on the critical topic of patient safety, is included in hospitals' FY 2015 TPSs and, therefore, will become a focus of quality improvement efforts. We note further that we examined the independent analysis of this measure's reliability provided by Mathematica Policy Research, entitled, ''Reporting Period and Reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised,'' which is available on our Web site (*http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf*), and which concluded that the measure achieves moderate reliability for the majority of hospitals for reporting periods of 6 months or longer. Based on this analysis, as well as our objective to include patient safety measures in the Hospital VBP Program, we believe that the proposed nearly 9-month performance period for this measure will produce reliable results for hospitals.

We welcome public comment on these proposals.

(3) CLABSI Measure

We posted CLABSI measure data on *Hospital Compare* on January 26, 2012. Pursuant to our commitment to post measure data on *Hospital Compare* at least one year prior to the beginning of a performance period for the Hospital VBP Program, the earliest we can begin a performance period for this measure is January 26, 2013. Because, as described above, we believe this measure captures important patient safety data, in this case related to infections that present the possibility of significant harm to hospitalized patients, we believe it is appropriate to adopt the measure as soon as possible for as lengthy a performance period as possible. Adopting an approximately 11-month performance period for this measure will not, in our view, appreciably harm the measure's statistical reliability for purposes of value-based purchasing scoring, particularly because (as described below) we are also proposing to adopt the measure steward's criteria for minimum number of cases to receive a measure score.

Therefore, we are proposing to adopt an approximately 11-month performance period for the CLABSI measure from January 26, 2013 through December 31, 2013 with a comparable baseline period of January 26, 2011 through December 31, 2011 for purposes of calculating the performance standards.

We welcome public comment on these proposals.

The proposed performance and baseline periods for all proposed FY 2015 measures appear below:

Domain	Baseline period	Performance period
Clinical Process of Care	January 1, 2011–December 31, 2011	January 1, 2013–December 31, 2013.
• AMI–10*	• April 1, 2011–December 31, 2011	• April 1, 2013–December 31, 2013.
Patient Experience of Care	January 1, 2011–December 31, 2011	January 1, 2013–December 31, 2013.
Outcome:		
• Mortality	• October 1, 2010–June 30, 2011	• October 1, 2012–June 30, 2013.
• AHRQ	• October 15, 2010–June 30, 2011	• October 15, 2012–June 30, 2013.
• CLABSI	• January 26, 2011–December 31, 2011	• January 26, 2013–December 31, 2013.
Efficiency:		
• Medicare Spending Per Beneficiary-1	• May 1, 2011–December 31, 2011	• May 1, 2013–December 31, 2013.

*As discussed further above, we are proposing a separate performance period for the AMI–10 measure. The proposed 12-month performance period specified above would apply to all other clinical process of care measures.

e. Proposed Performance Periods for Proposed FY 2016 Measures

In order to provide relatively more reliable data for the three proposed 30-day mortality measures and the AHRQ PSI composite measure, we considered how we could adopt a 24-month performance period for the FY 2016 Hospital VBP Program. We do not believe it is feasible to do so at this time given the statutory requirement that we establish and announce performance standards at least 60 days in advance of the applicable performance period. However, we intend to propose to adopt a 24-month performance period for these measures as soon as is practicable and will consider a 24-month performance period in future rulemaking.

Given the time constraints associated with the annual IPPS/LTCH PPS rulemaking schedule, we believe that the longest performance period we can propose for FY 2016 at this time is 21 months. We believe that this performance period will provide relatively more reliable measure data and will enable us to consider adopting a 24-month performance period in the future.

We therefore are proposing to adopt a 21-month performance period for the three proposed 30-day mortality measures and the AHRQ PSI composite measure for the FY 2016 Hospital VBP Program, from October 1, 2012 through July 30, 2014. We are further proposing a baseline period of October 1, 2010 through July 30, 2011, for purposes of calculating performance standards and measuring improvement. We note that this baseline period is identical to the proposed baseline period for these

measures for FY 2015. We also note that this baseline period is shorter than the proposed performance period. We believe it is appropriate to use the most recently-available data to calculate performance standards and are concerned about the possibility of using data from several years prior to the performance period for performance standards. However, we seek public comment on whether we should adopt a 24-month baseline period.

The table below displays the proposed performance period for the FY 2016 mortality and AHRQ PSI composite measures.

Measure	Baseline period	Performance period
Mortality/AHRQ PSI	October 1, 2010–June 30, 2011	October 1, 2012–June 30, 2014.

We welcome public comment on this proposal. We also seek comments on the possibility of adopting a ''rolling'' 2-year performance period for certain claims-based measures during which we would score hospitals using 24 months of data. As an example, under such a policy for mortality measures, hospitals could be scored for the FY 2018 Hospital VBP Program using data from the performance periods for FY 2017 (while not yet proposed, one possibility for that year could be July 1, 2013 through June 30, 2015). For subsequent fiscal years, we would drop the oldest 12 months of data from that period and add the next 12 months. The performance period for the FY 2019 Hospital VBP Program under that policy could be July 1, 2014 through June 30, 2016.

11. Proposed Performance Standards for the Hospital VBP Program for FY 2015 and FY 2016

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established and announced not later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513). In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement. We are proposing to codify this for performance standards in our regulations at § 412.165.

b. Proposed Performance Standards for the FY 2015 Hospital VBP Program Measures

We are proposing to establish performance standards that apply to the FY 2015 Hospital VBP Program using the same methodologies that we previously adopted for the FY 2013 and FY 2014 programs. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for a detailed discussion of the methodology we adopted for the clinical process of care, patient experience of care, and outcome measures, and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) for a discussion of the methodology we adopted for the Medicare spending per beneficiary measure.

We continue to believe that the finalized methodology for calculating performance standards is appropriate for the Hospital VBP Program given that the program remains relatively new to hospitals and the public. The proposed performance standards for the clinical process, outcome, and Medicare spending per beneficiary measures appear in the first table below, while the proposed performance standards for the patient experience of care (HCAHPS survey) measure appears in the second table below. We note that the performance standards displayed below represent estimates based on the most recently-available data; we will update the standards in the FY 2013 IPPS/LTCH PPS final rule. We also note that the performance standards for the CLABSI measure and the AHRQ PSI composite measure are calculated with lower values representing better performance, in contrast to other measures, on which higher values indicate better performance.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2015 HOSPITAL VBP PROGRAM CLINICAL PROCESS OF CARE AND OUTCOME DOMAINS, AND THE MEDICARE SPENDING PER BENEFICIARY MEASURE

Measure ID	Description	Achievement threshold	Benchmark
Clinical Process of Care Measures			
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.72727	1.00000
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.92857	1.00000
AMI–10	Statin Prescribed at Discharge	0.90474	
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	0.97129	1.00000
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.93671	0.99832
SCIP–Card–2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.	0.95122	1.00000
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.	0.97872	1.00000
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients	0.97882	1.00000
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.	0.96154	0.99905
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.	0.94799	0.99824

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2015 HOSPITAL VBP PROGRAM CLINICAL PROCESS OF CARE AND OUTCOME DOMAINS, AND THE MEDICARE SPENDING PER BENEFICIARY MEASURE—Continued

Measure ID	Description	Achievement threshold	Benchmark
SCIP–Inf–9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2.	0.93333	1.00000
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	0.94118	0.99938
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	0.8477	0.8673
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate	0.8861	0.9042
MORT–30–PN	Pneumonia (PN) 30-Day Mortality Rate	0.8818	0.9021
PSI–90	Patient safety for selected indicators (composite)	0.4006	0.2754
CLABSI	Central Line-Associated Blood Stream Infection	0.442	0.000
Efficiency Measures			
MSPB–1	Medicare Spending per Beneficiary	Median Medicare spending per beneficiary ratio across all hospitals during the performance period	Mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals during the performance period.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2015 HOSPITAL VBP PROGRAM PATIENT EXPERIENCE OF CARE DOMAIN

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	49.22	76.28	85.56
Communication with Doctors	57.31	79.61	88.72
Responsiveness of Hospital Staff	34.83	62.75	78.59
Pain Management	43.05	69.24	78.24
Communication about Medicines	28.11	60.46	71.72
Hospital Cleanliness & Quietness	40.35	63.79	78.46
Discharge Information	55.10	83.29	89.60
Overall Rating of Hospital	29.26	67.73	83.13

We welcome public comment on these proposed performance standards.

We are also aware that once the ICD–10–CM/PCS coding transition is completed, we will be faced with comparing hospitals' performance from baseline periods coded using ICD–9–CM with performance periods coded using ICD–10–CM/PCS. We note that constructing performance standards from such baseline periods could produce unforeseen consequences for quality measurement and performance scoring. Therefore, we seek comments on how to fairly compare hospitals' performance on quality measures when captured in different coding sets.

c. Proposed Performance Standards for FY 2016 Hospital VBP Program Measures

As described further above, in this proposed rule, we are proposing to adopt the three 30-day mortality measures and the AHRQ PSI composite measure for the FY 2016 Hospital VBP Program. We therefore must also propose performance standards for these measures based on the proposed baseline periods outlined above. Proposed performance standards for these measures appear in the table below. We note that the performance standards displayed below represent estimates based on the most recently-available data; we will update the standards in the FY 2013 IPPS/LTCH PPS final rule. We also note that the performance standards for the AHRQ PSI composite measure are calculated with lower values representing better performance, in contrast to the mortality measures, on which higher values indicate better performance.

PROPOSED PERFORMANCE STANDARDS FOR FY 2016 HOSPITAL VBP PROGRAMS OUTCOME DOMAIN: MORTALITY/PSI COMPOSITE MEASURES

Measure ID	Description	Achievement threshold	Benchmark
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.8477	0.8673
MORT–30–HF	Heart Failure (HF) 30-day mortality rate	0.8861	0.9042

PROPOSED PERFORMANCE STANDARDS FOR FY 2016 HOSPITAL VBP PROGRAMS OUTCOME DOMAIN: MORTALITY/PSI COMPOSITE MEASURES—Continued

Measure ID	Description	Achievement threshold	Benchmark
MORT–30–PN	Pneumonia (PN) 30-day mortality rate	0.8818	0.9021
PSI–90	Patient safety for selected indicators (composite)	0.4006	0.2754

d. Adopting Performance Periods and Standards for Future Program Years

For prior program years, with the exception of the Hospital Inpatient VBP Program proposed and final rule, we have proposed and finalized policies for the Hospital VBP Program in the IPPS/LTCH PPS and OPPS/ASC regulations. However, we do not believe these two rulemaking vehicles are ideally suited for additional Hospital VBP proposals. While we are aware that it is convenient for the public when additional proposals are made in a relatively limited number of rulemaking vehicles, we are concerned about the limitations that these regulations' schedules place on our ability to propose and finalize quality measures, performance periods, and performance standards in a timely manner.

In order to facilitate quality measure adoption for the Hospital VBP Program and ensure that hospitals are kept fully aware of the performance standards to which we intend to hold them accountable and the performance periods during which their performance will be measured, we are proposing to update performance periods and performance standards for future program years via notice on our Web site or another publicly-available Web site. We would establish future performance standards for the clinical process of care, outcome, and patient experience of care measures using the same methodology that we first finalized in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26513). We would establish future performance standards for the Medicare spending per beneficiary measure using the same methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656). In the case of other types of measures whose scoring would not be appropriately described by the methodologies outlined above, we intend to propose and finalize additional scoring methodologies.

We believe that this proposal will enable us to adopt measures representing the best in medical practice into the Hospital VBP Program more quickly and will allow us to establish and announce performance standards and performance periods when necessary outside the annual IPPS/LTCH PPS and OPPS/ASC rulemaking schedules. We believe this flexibility is especially necessary as the Hospital VBP Program continues to evolve and incorporate new types of quality measures.

We welcome public comment on this proposal.

12. Proposed FY 2015 Hospital VBP Program Scoring Methodology

a. General Hospital VBP Program Scoring Methodology

In the Hospital Inpatient VBP Program final rule, we adopted a methodology for scoring clinical process of care, patient experience of care, and outcome measures. As noted in that rule, this methodology outlines an approach that we believe is well understood by patient advocates, hospitals, and other stakeholders because it was developed during a lengthy process that involved extensive stakeholder input, and was based on a scoring methodology we presented in a report to Congress. We also noted in that final rule that we had conducted extensive additional research on a number of other important methodology issues to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for reasons of simplicity, transparency, and consistency, it is important to score hospitals using the same general methodology each year, with appropriate modifications to accommodate new domains and measures. We finalized a scoring methodology for the Medicare spending per beneficiary measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656).

For the FY 2015 Hospital VBP Program, we are proposing to use these same scoring methodologies to score hospital performance. We believe these scoring methodologies continue to appropriately capture hospital quality as reflected by the finalized quality measure sets. We also note that re-adopting the finalized scoring methodology from prior program years represents the simplest and most consistent policy for providers and the public.

b. Proposed Domain Weighting for the FY 2015 Hospital VBP Program for Hospitals That Receive a Score on All Four Proposed Domains

As we stated in the Hospital Inpatient VBP Program final rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care, and functional status measures (for example, measures assessing physical and mental capacity, capability, well-being and improvement). We took these considerations into account when developing the domain weighting proposal outlined below.

As discussed above, we are proposing to add the Efficiency domain to the Hospital VBP Program beginning with the FY 2015 program. Therefore, we are proposing the following domain weights for the FY 2015 program for hospitals that receive a score on all four proposed domains:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2015 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL PROPOSED DOMAINS

Domain	Weight (percent)
Clinical Process of Care	20
Patient Experience of Care	30
Outcome	30
Efficiency	20

We believe this domain weighting appropriately reflects our priorities for quality improvement in the inpatient hospital setting and aligns with the National Quality Strategy's priorities. We believe that the proposed domain weighting will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient experience. We note that the proposed domain weighting places the strongest relative emphasis on outcomes and the patient experience, which we view as two critical components of quality improvement in the inpatient hospital

setting. We further note that the proposed domain weighting, for the first time, incorporates a measure of efficiency and continues to provide substantial weight to clinical processes. We welcome public comment on this proposed weighting methodology.

c. Proposed Domain Weighting for Hospitals Receiving Scores on Fewer Than Four Domains

In prior program years, we finalized a policy that hospitals must have received domain scores on all finalized domains in order to receive a TPS. However, since the Hospital VBP Program has evolved from its initial two domains to an expanded measure set with four quality domains, we considered whether it was appropriate to continue this policy.

As described further below, we are proposing a higher minimum number of cases for the three 30-day mortality measures for FY 2015 than was finalized for the FY 2014 program in order to improve these measures' reliability given the relatively shorter proposed performance period described above. However, we are concerned that the relatively higher minimum number of cases could result in a substantially larger number of hospitals being excluded from the Hospital VBP Program. We believe that we should make a concerted effort to include as many hospitals as possible in the Program in order to offer quality incentives to as many hospitals as possible and encourage quality improvement as broadly as possible throughout the health care system while maintaining our focus on measure and scoring reliability.

Therefore, we are proposing that, for the FY 2015 Hospital VBP Program and subsequent fiscal years, hospitals with sufficient data to receive at least two domain scores (that is, sufficient cases and measures to receive a domain score on at least two domains) will receive a TPS. We also are proposing that, for hospitals with at least two domain scores, TPSs will be reweighted proportionately to the scored domains to ensure that the TPS is still scored out of a possible 100 points and that the relative weights for the scored domains remain equivalent to the proposed weighting outlined above. We believe that this proposal allows us to include relatively more hospitals in the Hospital VBP Program while continuing to focus on reliably scoring hospitals on their quality measure performance.

We welcome public comment on this proposal.

13. Applicability of the Hospital VBP Program to Hospitals

a. Background

Section 1886(o)(1)(C) of the Act specifies how the Hospital VBP Program applies to hospitals. Specifically, the term ''hospital'' is defined under section 1886(o)(1)(C)(i) of the Act as a ''subsection (d) hospital (as defined in section 1886(d)(1)(B [of the Act])).'' Section 1886(o)(1)(C)(ii) of the Act sets forth a list of exclusions to the definition of the term ''hospital'' with respect to a fiscal year, including a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program), a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients, a hospital for which there are not a minimum number of measures that apply to the hospital for the applicable performance period for the fiscal year, and a hospital for which there are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In addition, section 1886(o)(1)(C)(iv) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, the Secretary may exempt the hospital from the Hospital VBP Program if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. We interpret the reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

b. Proposed Exemption Request Process for Maryland Hospitals

Acute care hospitals located in the State of Maryland are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26530), we finalized our policy that the Hospital VBP Program would apply to acute care hospitals located in the State of Maryland unless the Secretary exercises discretion pursuant to section 1886(o)(1)(C)(iv) of the Act. We also finalized a procedure for the State to submit a report pursuant to section 1886(o)(1)(C)(iv) of the Act in a timeframe that would allow it to be received no later than October 1, 2011, which is the beginning of the fiscal year prior to FY 2013.

We received an FY 2013 exemption request from the Maryland Health Services Cost Review Commission (MHSCRC) on September 30, 2011 and the Secretary approved the exemption request in December 2011. This report included a discussion on how the state program achieved or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. When evaluating the MHSCRC's request, we considered the relevant health outcomes for the State's hospitals as described in the MHSCRC's request and noted that they achieve or surpass the current national results for Hospital VBP FY 2013 clinical process of care and HCAHPS dimensions. We also assessed closely-related clinical outcomes as measured by quality data reported through the Hospital IQR Program. For the FY 2013 Hospital VBP Program, however, we did not assess the criterion ''cost savings'' as required by the statute, as the FY 2013 Hospital VBP Program does not use any efficiency measures and is a budget-neutral program pursuant to section 1886(o)(7)(A) of the Act. Maryland hospitals are therefore exempt from the FY 2013 Hospital VBP Program.

Beginning with the FY 2014 program, we are proposing to adopt a new procedure for submission of the report in order for a hospital within the State to be exempt from the Hospital VBP Program. Under this proposed procedure, if the State seeks an exemption with respect to a particular program year, it would need to submit a report that meets the requirements of section 1886(o)(1)(C)(iv) of the Act in a timeframe that allows it to be received by the Secretary on or before November 15 prior to the effective fiscal year (for example, the report seeking an exemption from the FY 2014 program would have to be received by the Secretary no later than November 15, 2012). We anticipate notifying the State, as well as each hospital for which the State has requested an exemption, of our decision whether to grant the request no later than 90 days following the exemption request deadline.

We will evaluate each exemption request to see if the State has demonstrated that it has implemented a similar program for participating hospitals that achieves or surpasses the measured results in terms of patient health outcomes and cost savings relative to the Hospital VBP Program.

We welcome public comment on our proposals.

14. Proposed Minimum Numbers of Cases and Measures for the FY 2015 Hospital VBP Program

a. Background

Section 1886(o)(1)(C)(ii)(III) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year. Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we finalized minimum numbers of 10 cases and 4 measures in the clinical process of care domain and 100 completed HCAHPS surveys for the patient experience of care domain. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74534), we finalized a minimum number of 10 cases for the three 30-day mortality measures. We also finalized a minimum number of 2 measures with respect to the Outcome domain. In both rules, we finalized a policy that hospitals must have sufficient cases and measures in all domains in order to receive a TPS.

b. Proposed Minimum Numbers of Cases and Measures for the FY 2015 Outcome Domain

As described further above, we are proposing a 9-month performance period for the three 30-day mortality measures for the FY 2015 Hospital VBP Program. We have reassessed the previously finalized 10 case minimum threshold for the three 30-day mortality measures (76 FR 74533 through 74534), as well as reexamining the independent analyses by Brandeis University and Mathematica Policy Research, when considering these three measures' proposed addition. We recognize that the proposed 9-month performance period for these measures would increase the number of hospitals with insufficient cases on the measure (that is, between 10 and 24) to several hundred hospitals, based on past information. We believe that this proposal fulfills our intent to link patient outcomes with payment, relative to reliability and seasonality concerns from using a 9-month performance period.

In order to ensure that the mortality measure scores remain sufficiently reliable, we are proposing to adopt a 25-case minimum for the three 30-day mortality measures for FY 2015. We believe that this proposal will ensure relatively more reliable measure data than could be obtained with the 10-case minimum as has been finalized for FY 2014 given the relatively shorter proposed performance period. As described above, while this may result in fewer hospitals receiving scores on the mortality measures, we have proposed to reallocate domain weighting for hospitals with fewer domain scores than the total number of finalized domains. By doing so, we believe we are appropriately allowing as many hospitals as possible to participate in the Hospital VBP Program while also ensuring reliable quality measure and quality domain data.

We note that this proposed minimum number of cases is higher than has been finalized for other types of measures such as clinical process of care measures. However, we note that clinical process of care measures are not risk-adjusted and are not outcome-based. Because those measures do not require statistical adjustment to estimate hospital-specific differences in case mix, we believe that the relatively smaller case minimum is acceptable for clinical process of care measures.

For the AHRQ PSI composite measure, we are proposing to adopt AHRQ's methodology, which uses three cases for any of the underlying indicators as a case minimum. For the CLABSI measure, we are proposing to adopt CDC's minimum case criteria, which calculates a standardized infection ratio for a hospital on the CLABSI measure if the hospital has 1 predicted infection during the applicable period. We believe that the measure stewards' methodologies for constructing reliable measure data are most appropriate for use in the Hospital VBP Program. Further information on these measures may be found on the QualityNet Web site.

In the CY 2012 OPPS/ASC final rule with comment period, we concluded based on an independent analysis that the minimum number of measures that a hospital must report in order to receive a score on the outcome domain is two measures. We continue to believe that this minimum number is appropriate for the expanded outcome domain because adding measure scores beyond the minimum number of measures has the effect of enhancing the domain score's reliability. For that reason, we are proposing to adopt it for the FY 2015 Hospital VBP Program.

We welcome public comment on these proposals.

c. Proposed Medicare Spending per Beneficiary Measure Case Minimum

As required by section 1886(o)(1)(C)(iii) of the Act, we obtained an independent analysis to help us determine the appropriate minimum number of cases for the Medicare spending per beneficiary measure. For this measure, we are proposing to interpret the term ''case'' in section 1886(o)(1)(C)(ii)(IV) of the Act as a Medicare spending per beneficiary episode. A Medicare spending per beneficiary episode is inclusive of all Part A and Part B payments from 3 days prior to a subsection (d) hospital admission through 30 days post discharge with certain adjustments and exclusions. The independent analysis examines the tradeoff between: Increasing the minimum number of episodes, which shrinks the confidence interval; and reducing the minimum number of episodes, which widens the confidence interval but enables more hospitals to receive a Medicare spending per beneficiary measure score. Because the distribution of Medicare spending per beneficiary episodes is skewed towards higher cost episodes, creating confidence intervals using statistical techniques that assume spending is normally and symmetrically distributed will not accurately describe the likelihood a hospital's true efficiency level falls within the confidence interval bounds.

To account for these statistical issues, the independent analysis uses a simulation-based (''non-parametric bootstrap'') methodology to measure how the confidence interval of the Medicare spending per beneficiary measure changes when the minimum episode threshold increases. Medicare spending per beneficiary is measured for an ''average'' hospital, where the ''average'' hospital case is considered one with a Medicare spending per beneficiary episode distribution that mimics that of the entire population of Medicare spending per beneficiary episodes. This methodology simulates the process of randomly drawing Medicare spending per beneficiary episodes from the population, and thus approximates the actual shape of the Medicare spending per beneficiary measure distribution from which confidence intervals are determined. By repeatedly calculating (in this case, 10,000 times for each minimum episode threshold) a Medicare spending per beneficiary measure for this simulated hospital under differing assumptions on the number of episodes observed, one

can create a confidence interval for the Medicare spending per beneficiary measure of this ''average'' hospital. The upper and lower bounds of the 95 percent confidence interval indicates that 95 percent of the time, the hospital's Medicare spending per beneficiary measure will fall within this range when the minimum number of cases (the minimum episode threshold) is set at different levels. As the minimum episode threshold increases, the width of the confidence interval becomes narrower, but the number of hospitals receiving a Medicare spending per beneficiary measure score decreases.

In developing our proposal, we considered two options for setting the minimum number of cases for the Medicare spending per beneficiary measure: (1) Setting the minimum number of cases at 25; and, (2) setting the minimum number of cases at 50.

We focused on these minimums because we believe that either of them provides a sufficiently narrow range at the 95 percent confidence interval. The independent analysis concludes that if the minimum number of cases is set at 25, then 95 percent of the time a hospital with an average underlying efficiency level (that is, 1.0) would receive an Medicare spending per beneficiary measure score between 0.81 and 1.23. Further, a minimum number of 25 cases would enable 97.8 percent of hospitals to receive a Medicare spending per beneficiary measure score, based on historical data. The analysis also showed that the alternative minimum of 50 cases would result in a 95 percent confidence interval range of 0.86 to 1.16 and would enable 95.9 percent of hospitals to receive a Medicare spending per beneficiary measure score, based on historical data.

After considering the options outlined above, we are proposing to use 25 as the minimum number of cases required in order to receive a score for the Medicare spending per beneficiary measure. We believe that using a minimum number of 25 cases achieves an appropriate balance of our interest in allowing the maximum possible number of hospitals the opportunity to receive a score on the Medicare spending per beneficiary measure and maintaining a sufficiently narrow range for the 95 percent confidence interval. Additionally, although we are proposing to use a minimum of 25 cases for the Medicare spending per beneficiary measure, we also seek comment on whether using a minimum of 50 cases better reaches our goal of maintaining a meaningful measure of Medicare spending across hospitals.

15. Immediate Jeopardy Citations

Under section 1886(o)(1)(C)(ii)(II) of the Act, a hospital is excluded from the Hospital VBP Program if it has been cited by the Secretary during the performance period for deficiencies that pose immediate jeopardy to the health or safety of patients. In the Hospital Inpatient VBP Program final rule (76 FR 26528 through 26530), we finalized our interpretation of this provision to mean that any hospital that we cite through the Medicare State Survey and Certification process for deficiencies during the performance period that pose immediate jeopardy to patients will be excluded from the Hospital VBP Program for the fiscal year. We also finalized our proposal to use the definition of the term ''immediate jeopardy'' that appears in 42 CFR 489.3.

In proposed § 412.160 we are proposing to define ''immediate jeopardy'' in the same way as that term is defined in 42 CFR Part 489, which governs provider agreements and supplier approval. We believe that the language in section 1886(o)(1)(C)(ii)(II) of the Act referring to a hospital having been ''cited'' for deficiencies posing an immediate jeopardy is a reference to the process by which CMS, through agreements with State survey agencies, surveys or inspects hospitals for compliance with the hospital conditions of participation at 42 CFR Part 482 or Emergency Medical Treatment and Labor Act (EMTALA) regulations at § 489.24, and issues deficiency citations for non-compliance with Federal health, safety and quality standards. The survey process is governed by provisions found in 42 CFR Part 488, Survey, Certification and Enforcement Procedures. Further, provisions at 42 CFR Part 489, Provider Agreements and Supplier Approval, define the term ''immediate jeopardy'' at § 489.3; authorize us at § 489.53(a)(3) to terminate the Medicare provider agreement for the hospital's failure to meet the conditions of participation; authorize us at § 489.53(b) to terminate the Medicare provider agreement of a hospital that fails to meet the EMTALA regulatory requirements; and provide at § 489.53(d)(2)(i) for a shortened advance notice to the public of the termination when a hospital with an emergency department is in violation of EMTALA requirements and the violation poses immediate jeopardy. Therefore, we believe that the term ''immediate jeopardy'' should be defined in our Hospital VBP Program regulations in the same manner as it is defined for the purpose of survey, certification, enforcement, and termination procedures.

In § 412.160, we are proposing to define the phrase ''cited for deficiencies that pose immediate jeopardy.'' We are proposing a definition in order to avoid potential ambiguities about the terms ''cited'' and ''deficiencies.'' There are several ways in which a hospital might be found to have an immediate jeopardy situation. Appendix Q of the State Operations Manual (SOM), Pub. No. 100–07, provides guidance to the State survey agencies on our policies concerning the identification and citation of immediate jeopardy and subsequent enforcement actions. The most common way in which an immediate jeopardy situation is identified is when a surveyor or team of surveyors is in the process of conducting a survey at the hospital and accurately identifies those situations which immediately jeopardize the health and safety of patients. Surveyors may be expected, according to State protocols, to consult immediately with their supervisors before declaring an immediate jeopardy, and in cases involving hospitals deemed to meet the conditions of participation based on their accreditation, the State must first consult with the CMS Regional Office (RO).

Once an immediate jeopardy is declared, the hospital's management is informed and expected to take steps to remove the immediate jeopardy, preferably before the survey team concludes the on-site portion of its survey. If the hospital does not remove the immediate jeopardy while the survey team is on-site, it has 23 days to submit an acceptable plan of correction and have an onsite follow-up survey to confirm removal. If the hospital fails to remove the immediate jeopardy in a timely manner, we may terminate the hospital's Medicare provider agreement. There are also situations where a survey team does not declare an immediate jeopardy while on-site, but a subsequent supervisory or CMS RO review of the survey team's findings identifies an immediate jeopardy situation that should have been declared. In such cases, the hospital is promptly advised of the immediate jeopardy and given 23 days to submit an acceptable plan of correction and have an onsite follow-up survey to confirm removal of the immediate jeopardy. It can also happen that a supervisory or CMS RO review will conclude that the survey documentation does not support a finding of an immediate jeopardy, and in such cases no official immediate jeopardy citation will be issued.

It should be noted that removal of an immediate jeopardy is not necessarily the same as correction of the hospital's

noncompliance deficiencies. Removal may be accomplished by an interim measure while the hospital works to create a systematic and permanent correction of its deficient practices.

The Form CMS–2567, Statement of Deficiencies and Plan of Correction, is issued after each survey of a hospital, even if only to indicate that no deficiencies were found during the survey (SOM Section 2728 and SOM Exhibit 7A, Principles of Documentation, Principle #1). The CMS–2567 form constitutes the official notice to a healthcare facility of the survey findings. Statements made by surveyors to the facility while they are on-site are always preliminary in nature. After surveyors have exited the facility, they prepare the Form CMS–2567 based on their observations and survey documentation. Their draft Form CMS–2567 is then subjected to a supervisory review and, in the case of hospitals that are deemed to meet the conditions of participation via accreditation and are being cited for serious noncompliance (that is, condition-level or immediate jeopardy citation), a CMS RO review. The Form CMS–2567 is not considered final until it is transmitted to the healthcare facility, either by the State survey agency or, in certain cases, the CMS RO.

In the case of a survey where an immediate jeopardy situation was found, the Form CMS–2567 must state that the facility was found to have immediate jeopardy. This is the case regardless of whether the immediate jeopardy was removed while the survey team was still on-site at the facility, although on-site removal will be noted if it occurred. Furthermore, it is standard survey practice to cite on the Form CMS–2567 all noncompliance deficiencies identified during a survey even when the healthcare facility corrects those deficiencies after they have been identified by a surveyor, but before the survey team exits the facility (SOM Exhibit 7A, Principles of Documentation, Principle #4).

We considered whether it would be reasonable to treat only those hospitals that failed to remove immediate jeopardy while a survey team was still on-site as having been ''cited for an immediate jeopardy'' solely for the purposes of the Hospital VBP Program. However, we concluded that this would not be equitable, since there are cases where an immediate jeopardy is identified after the survey team has left the hospital through a supervisory or CMS RO review, as described above. We also concluded this approach would not be consistent with the statutory requirement given that the Form CMS–2567 is the official notice to a healthcare facility of deficiencies found during a survey and in light of the fact that CMS includes references to the identification of an immediate jeopardy on the CMS–2567, regardless of when or if it was removed by the facility. We have, therefore, concluded that ''citation'' of an immediate jeopardy within the context of the Hospital VBP Program means the identification of an immediate jeopardy noted on the CMS–2567 that is issued to the hospital after a survey.

We also note that section 1886(o)(1)(C)(ii)(II) of the Act refers to the citation of plural ''deficiencies'' that pose immediate jeopardy and that this requires interpretation of its application to the Hospital VBP Program. We use an Automated Survey Processing Environment (ASPEN) system to catalog deficient practices identified during a survey and to generate the CMS–2567 that is issued to the hospital after the survey. To facilitate processing in the ASPEN system, we have subdivided the regulations applicable to each type of certified healthcare facility into specific ''tags,'' each one of which has corresponding interpretive guidelines in the applicable appendix of the SOM. Hospital tags are found in Appendix A. The ASPEN system also differentiates between ''condition'' and ''standard'' tags for non-long term care enforcement, since it is essential to know whether or not identified noncompliance is found at the condition-level, that is, whether it is considered substantial noncompliance. Each hospital condition of participation has its own condition tag. There are also a varying number of ''standard'' tags within each condition. The number of standard tags identified in the SOM Appendix does not correspond to the number of individual ''standards'' required in the regulations; usually there are more tags than standards, because standards may involve multiple items or requirements under specific conditions of participation that lend themselves to separate evaluation.

While we understand that each tag identified in a CMS–2567 may be viewed as a separate deficiency, we also recognize that the division of the regulations for each ''condition'' and ''standard'' into individual tags was to facilitate the survey and certification process for surveyors. Moreover, in general a set of documented deficient practices that constitute immediate jeopardy would be cited at least in two tags, since there must be a citation at the condition-level to indicate substantial noncompliance, along with citation of any pertinent standard-level tags, which are subsets of the condition tags. We do not believe it was the intent of the statute to count each of these tags related to the same set of circumstances or practices as separate deficiencies under the Hospital VBP Program.

We have concluded, therefore, that a more reasonable interpretation of the Hospital VBP statute is to view each hospital survey for which the CMS–2567 form cited immediate jeopardy as a deficiency. Thus, a hospital would have to have been cited on a CMS–2567 for immediate jeopardy on at least two surveys during the performance period in order to be considered as having multiple deficiencies that pose immediate jeopardy. Accordingly, we are proposing to define in our regulations the term ''cited for deficiencies that pose immediate jeopardy'' under the Hospital VBP Program as meaning that, during the applicable performance period, the hospital had more than one survey for which it was cited for an immediate jeopardy on the Form CMS–2567, Statement of Deficiencies and Plan of Correction.

As required by the statute, hospitals cited during the performance period for multiple deficiencies that pose immediate jeopardy to the health or safety of patients would be excluded from the Hospital VBP Program for the applicable fiscal year. Because we sometimes adopt different performance periods for different measures for purposes of the same program year, we are proposing to exclude hospitals cited for such deficiencies during any of the finalized performance periods for the applicable program year for purposes of that interpretation.

We welcome public comment on this interpretation of the immediate jeopardy exclusion and on our proposals.

D. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Statutory History

In accordance with section 1886(m)(5) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting (LTCHQR) Program. Under the LTCHQR Program, for rate year 2014 and each subsequent rate year, in the case of a long-term care hospital (LTCH) that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by two percentage points.

Section 1886(m)(5)(D)(iii) of the Act requires the Secretary to publish the selected measures for the LTCHQR Program that will be applicable with respect to FY 2014 no later than October 1, 2012.

Under section 1886(m)(5)(D)(i) of the Act, the quality measures for the LTCHQR Program are measures selected by the Secretary that have been endorsed by an entity that holds a contract with the Secretary under section 1890(a) of the Act, unless an exception under section 1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by the National Quality Forum (NQF). Section 1886(m)(5)(D)(ii) of the Act provides that an exception may be made in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity that holds a contract with the Secretary under section 1890(a) of the Act. In such a case, section 1886(m)(5)(D)(ii) of the Act authorizes the Secretary to specify a measure(s) that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The LTCHQR Program was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

2. LTCH Program Measures for the FY 2014 Payment Determination and Subsequent Fiscal Years Payment Determinations

a. Proposed Process for Retention of LTCHQR Program Measures Adopted in Previous Payment Determinations

For the LTCHQR Program, we are proposing that once a quality measure is adopted, it is retained for use in subsequent fiscal year payment determinations, unless otherwise stated. For the purpose of streamlining the rulemaking process, we are proposing that when we initially adopt a measure for the LTCHQR Program for a payment determination, this measure is automatically adopted for all subsequent payment determinations or until we propose to remove, suspend, or replace the measure. Quality measures may be considered for removal by CMS if: (1) Measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can be no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) if a measure that is more strongly associated with desired patient outcomes for the particular topic is available; or (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. For any such removal, the public will be given a chance to comment through the annual rulemaking process. However, if there is reason to believe continued collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from LTCHQR Program and not wait for the annual rulemaking cycle. Such measures will be promptly removed with LTCHs and the public being immediately notified of such a decision through the usual LTCHQR Program communication channels, including listening session, memos, email notification, and Web posting and their removal formally announced in the next annual rulemaking cycle.

We are inviting public comment on our proposal that once a quality measure is adopted, it is retained for use in the subsequent fiscal year payment determinations unless otherwise stated.

b. Proposed Process for Adoption of Changes to LTCHQR Program Measures

As mentioned previously, quality measures selected for the LTCHQR Program must be endorsed by the NQF unless they meet the statutory criteria for exception. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process (*http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx*). The NQF undertakes review of: (a) New quality measures and national consensus standards for measuring and publicly reporting on performance, (b) regular maintenance processes for endorsed quality measures, (c) measures with time limited endorsement for consideration of full endorsement, and (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review (*http://www.qualityforum.org/Measuring_Performance/Ad_Hoc_Reviews/Ad_Hoc_Review.aspx*).

The NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to NQF on an annual basis. As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF Technical Expert panel which, in turn, provides input to the Consensus Standards Approval Committee which then makes a decision on endorsement status and/or specification changes for the measure, practice, or event.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the LTCHQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the LTCH Quality Reporting Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on our LTCH Quality Reporting Web site at: *http://www.cms.gov/LTCH–Quality-Reporting/*. We would provide sufficient lead time for LTCH to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF-endorsed LTHCQR Program measures in

the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

3. Proposals for the FY 2014 LTCHQR Program

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756), we adopted three quality measures for the FY 2014 payment determination as listed in the following table:

PREVIOUSLY FINALIZED QUALITY MEASURES FOR THE FY 2014 PAYMENT DETERMINATION

NQF #0138	Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1,000 urinary catheter days, for Intensive Care Unit [ICU] Patients.
NQF #0139	Central Line Catheter-Associated Blood Stream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients.
NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay).

The three measures finalized for FY 2014 payment determination were NQF-endorsed at the time, although not for the LTCH setting. We also stated that we expected the NQF would review some of these measures for applicability to the LTCH setting and we anticipated this review might result in modifications to one or more of the measures.

As part of its endorsement maintenance process, under NQF's Patient Safety Measures Project (*http://www.qualityforum.org/projects/patient_safety_measures.aspx*), the NQF reviewed the CAUTI and CLABSI measures previously adopted and expanded the scope of endorsement to include additional care settings, including LTCHs. The original NQF-endorsed numbers were retained for these two expanded measures, but the measures were retitled to reflect the expansion of the scope of endorsement: #0138 Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days, for Intensive Care Unit [ICU] Patients is now titled National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and #0139 (Central Line Catheter-Associated Blood Stream Infection [CLABSI] Rate for ICU and High-Risk Nursery (HRN) Patients is now titled National Health Safety Network (NHSN) Central-Line Associated Blood Stream Infection (CLABSI) Outcome Measure (*http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Patient_Safety_Measures.aspx*).

These expanded measures allow for the calculation of a standardized infection ratio (SIR).[120,121,122,123] For the remainder of this proposed rule, we refer to these measures as the CAUTI measure and CLABSI measure, respectively. We are proposing to adopt the changes to the NQF-endorsed CAUTI and CLABSI measures that we previously finalized for the FY 2014 payment determination, consistent with our stated intention to update these measures with changes resulting from NQF's review of the measures. Further, we are proposing to adopt the NQF-endorsed CAUTI measure and CLABSI measure for the FY 2015 payment determination and all subsequent fiscal year payment determinations. We also are proposing to incorporate any future changes to the CAUTI measure and CLABSI measure to the extent these changes are consistent with our proposal in section VIII.D.2.b. of this preamble to update measures.

We are proposing to retain the measure Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), as finalized in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination, for FY 2015 and all subsequent fiscal year payment determinations. We also note that the Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) measure is undergoing NQF review for expansion in the scope of endorsement to include additional care settings, including LTCHs and, to the extent that the measure is updated in a manner that does not substantially change the nature of the measure, we would incorporate the updates consistent with our previous proposal to update measures. For the remainder of this proposed rule, we refer to this measure as the Pressure Ulcer measure. For more information on the history of this measure in the LTCHQR Program, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51753 through 51756).

We invite public comment on our proposal to adopt the revised CAUTI measure (NQF #0138) and CLABSI measure (NQF #0139) beginning with the FY 2014 payment determination. We also invite public comment to retain the Pressure Ulcer measure (NQF #0678) (which was finalized last year for the FY 2014 payment determination) for the FY 2015 payment determination and subsequent fiscal year payment determinations, as shown in the following table.

PROPOSED QUALITY MEASURES TO BE RETAINED FOR THE FY 2014 AND SUBSEQUENT FISCAL YEAR PAYMENT DETERMINATIONS

NQF #0138	National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.
NQF #0139	National Health Safety Network (NHSN) Central Line Associated Blood Stream Infection (CLABSI) Outcome Measure.
NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay).

[120] Centers for Disease Control and Prevention. (2012, January). Central Line-Associated Bloodstream Infection (CLABSI) Event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

[121] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0139.*

[122] Centers for Disease Control and Prevention. (2012, January). Catheter Associated Urinary Tract Infection Event. Retrieved from: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

[123] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0138.*

We are proposing to use the same data collection and submission methods finalized for these measures (CAUTI, CLABSI and Pressure Ulcer) in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51752 through 51756). We are proposing that data collection for these measures, if they be adopted in the FY 2013 IPPS/LTCH PPS final rule, remain the same for FY 2014 payment determination and all subsequent fiscal year payment determination.

For the proposed CAUTI measure and CLABSI measure, the measure specifications are available on the NQF Web site at: *http://www.qualityforum.org/QPS/0138* and *http://www.qualityforum.org/QPS/0139*, respectively. The data collection and reporting requirements for CAUTI and CLABSI are available at *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf* and *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*, respectively.

For the Pressure Ulcer measure, the data collection instrument is the Long-Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (CARE) Data Set available for download at *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA–Listing-Items/CMS1252160.html*.[124] Because there are no mandatory standardized data sets being used in LTCHs, we created a new data set, the LTCH CARE Data Set, for use in LTCHs for data reporting for the Pressure Ulcer measure beginning October 1, 2012. This data set incorporates data items contained in other, standardized and clinically established pressure ulcer data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE data set (Continuity Assessment Records & Evaluation). Beginning on October 1, 2012, LTCHs will begin to use a data collection document entitled the ''LTCH CARE Data Set'' as the vehicle by which to collect the data for the Pressure Ulcer measure for the LTCHQR Program. This data set consists of the following components: (1) Pressure ulcer documentation; (2) selected covariates related to pressure ulcers; (3) patient demographic information; and; (4) a provider attestation section.

The measure specifications for the LTCH CARE Data Set are available on our Web site for the LTCHQR Program at *http://www.cms.gov/LTCH-Quality-Reporting/*. The LTCH CARE Data Set Technical Specifications Draft Version 1.00.1 for the Pressure Ulcer measure are available at the LTCH Quality Reporting Technical Information Web page *http://www.cms.gov/LTCH-Quality-Reporting/05_LTCHTechnical Information.asp#TopOfPage*.

For detailed discussions of the history of the LTCHQR Program, including the statutory authority and further details on the three measures previously finalized for FY 2014 payment determination, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756). We have reproduced portion of the data collection and submission timeline finalized for FY 2014 payment determination in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756) in the following table.

TIMELINE FOR SUBMISSION OF DATA FOR THE LTCHQR PROGRAM FY 2014 PAYMENT DETERMINATION

Data collection timeframe: calendar year (CY) 2012	Final submission deadline for data related to the LTCH quality reporting program FY 2014 payment determination
Q4 (October 1–December 31, 2012).	May 15, 2013.

We refer readers to section VIII.D.5. of this preamble for the proposed timeline for data submission under the LTCHQR Program for the FY 2015 payment determination.

4. Proposed LTCHQR Program Quality Measures for the FY 2016 Payment Determinations and Subsequent Fiscal Years Payment Determinations

a. Considerations in Updating and Expanding Quality Measures under the LTCHQR Program for FY 2016 and Subsequent Payment Update Determinations

We believe that development of a LTCHQR Program that is successful in promoting the delivery of high quality healthcare services in LTCHs is paramount. We seek to adopt measures for the LTCHQR Program that promote better, safer, and more efficient care. Our measure development and selection activities for the LTCHQR Program take into account national priorities, such as those established by the National Priorities Partnership (*http://www.nationalprioritiespartnership.org/*), HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*), and the National Strategy for Quality Improvement in Healthcare (*http://www.healthcare.gov/center/reports/quality03212011a.html*). To the extent practicable, we have sought to adopt measures that have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

In addition, we consider input from the multi-stakeholder group, the Measures Application Partnership (MAP) (*http://www.qualityforum.org.map/*), in selecting measures for the LTCHQR program. Section 1890A(a)(1) of the Act, as added by section 3014(a) of the Affordable Care Act, requires the entity with a contract under section 1890(a) of the Act, currently NQF, to convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures. Section 1890A(a)(3) of the Act, as added by section 3014(b) of the Affordable Care Act, further requires the entity with a contract under section 1890(a) of the Act to transmit the input of the multistakeholder groups to the Secretary not later than February 1 of each year, beginning in 2012. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration the input of the multi-stakeholder groups in selecting quality and efficiency measures. The MAP is the public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input on measures as required by section 1890A(a)(3) of the Act. The MAP's input on quality and efficiency measures was transmitted to the Secretary and is available at (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*). As required by section 1890A(a)(4) of the Act, we considered the MAP's recommendations in selecting quality and efficiency measures for the LTCHQR Program.

b. Proposed New LTCHQR Program Quality Measures Beginning with the FY 2016 Payment Determination

For the FY 2016 payment determination and subsequent fiscal year payment determinations, in addition to retaining the three previously discussed measures (CAUTI measure, CLABSI measure and Pressure Ulcer measure), we are proposing to adopt five additional quality measures for the LTCHQR Program, see table below. Our proposal to add these five measures is part of our effort to promote overarching health care aims and goals in an effective and meaningful manner.

[124] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

We also seek to minimize the burden of data collection for LTCHs.

PROPOSED NEW QUALITY MEASURES FOR THE FY 2016 LTCHQR PROGRAM PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS

NQF measure ID	Measure title
NQF #0680	Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).
NQF #0682	Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay).
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel.
NQF #0302	Ventilator Bundle.
Not NQF endorsed	Restraint Rate per 1,000 Patient Days.

(1) Proposed New Quality Measure #1 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

According to the CDC, as of 2011, there are on average over 200,000 hospitalizations due to influenza every year.[125] The Agency for Healthcare Research and Quality (AHRQ) reports that, in 2004, there were more than 37,000 hospitalizations in which influenza was noted during the stay. For over 21,000 of these hospitalizations, influenza was listed as the primary diagnosis. The aggregate hospital costs for these roughly 21,000 hospitalizations were estimated at $146 million.[126]

Although influenza is prevalent among all population groups, the rates of death and serious complications related to influenza are highest among those age 65 and older and those with medical complications that put them at higher risk. The CDC reports that an average of 36,000 Americans die annually from influenza and its complications, and most of these deaths are among people 65 years of age and over.[127] In 2004, 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these were among the elderly.[128] Given that many individuals receiving health care services in LTCHs are elderly and/or have several medical conditions, many LTCH patients are within the target population for the influenza vaccination.[129,130] Healthy People 2010 (Objective 14–29) and Healthy People 2020 (Objective IID–12.8) each set a goal of 90 percent of adults vaccinated against pneumococcal disease in long-term care facilities.[131,132] However, among adults age 65 years and older, only 72.1 percent were vaccinated during the 2006–2007 influenza season and only 69.6 percent of adults age 65 years and older were vaccinated during the 2009–2010 influenza season.[133,134] According to information currently available on the Nursing Home Compare Web site (*http://www.medicare.gov/NHCompare*), the national average for the percentage of short-stay residents given the influenza vaccine is roughly 82 percent.[135] No comparable information is currently available on patients in the LTCH setting.

In light of the evidence outlined previously, particularly that many individuals receiving care in the LTCH setting are within the target population for influenza vaccination, we are proposing NQF #0680, Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay), for application in the LTCHQR Program for the FY 2016 payment determination and subsequent fiscal year payment determinations. We note that this measure is currently endorsed for short-stay nursing home residents, but believe this measure is highly relevant for the LTCH setting because, as stated above, many patients receiving care in the LTCH setting are elderly and within the target population for influenza vaccination. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[136]

Section 1886(m)(5)(D)(ii) of the Act, the exception authority provides that ''[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' We reviewed NQFs consensus endorsed measures and were unable to identify any NQF-endorsed measures for influenza vaccination in the LTCH setting. We are unaware of any other measures for influenza

[125] Centers for Medicare & Medicaid Services (2011, May). Adult immunization: Overview. Retrieved from *https://www.cms.gov/adultImmunizations/*.

[126] Milenkovic M, Russo CA, Elixhauser A. (2006). Hospital stays for influenza, 2004 (Healthcare Cost and Utilization Project statistical brief no. 16). Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb16.pdf*.

[127] Centers for Medicare & Medicaid Services (2011, May). Adult Immunization: Overview. Retrieved from *https://www.cms.gov/Immunizations/*.

[128] Gorina Y, Kelly T, Lubitz J, *et al.* (2008, February).Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from *http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf*.

[129] Centers for Disease Control and Prevention. (2008, September). Influenza e-brief: 2008–2009 flu facts for policymakers. Retrieved from *http://www.cdc.gov/washington/pdf/flu_newsletter.pdf*.

[130] Zorowitz, RD. Stroke Rehabilitation Quality Indicators: Raising the Bar in the Inpatient Rehabilitation Facility. Topics in Stroke Rehabilitation 2010; 17 (4):294–304.

[131] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (n.d.). Healthy People 2010 archive. Retrieved from *http://www.healthypeople.gov/2010/*.

[132] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and Infectious Diseases. Retrieved from *http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23*.

[133] Centers for Disease Control and Prevention. (2008). State specific influenza vaccination coverage among adults—United States, 2006–2007 influenza season. MMWR, 57(38), 1033–1039. Retrieved from *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5738a1.htm*.

[134] Centers for Disease Control and Prevention (2011, May). Seasonal influenza (flu): final estimates for 2009–10 seasonal influenza and influenza A (H1N1) 2009 monovalent vaccination coverage—United States, August 2009 through May 2010. Retrieved from *http://www.cdc.gov/flu/professionals/vaccination/coverage_0910estimates.htm*.

[135] Centers for Medicare & Medicaid Services. (2011). Nursing Home Compare. Available from *http://www.medicare.gov/NHCompare/*.

[136] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available from *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

vaccination in the LTCH setting that have been approved by a voluntary consensus standards body and endorsed by NQF. We are proposing to adopt the NQF-endorsed measure the Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) for application in the LTCH setting for the LTCHQR Program under the Secretary's authority to select non-NQF measures. This proposal is also consistent with the 2008 NQF steering committee recommendation that ''in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement.'' [137] Data on this measure is currently collected and reported as part of the Nursing Home Quality Initiative.

We are proposing that data for this measure will be collected using the same data collection and submission framework that we finalized for the FY 2014 payment determination.[138] We intend to revise the LTCH CARE data set to include new items which assess patients' influenza vaccination status should this proposed measure be adopted. These items will be based on the items from the Minimum Data Set (MDS) 3.0 items.[139] The specifications and data elements for this proposed measure are available in the MDS 3.0 QM User's Manual available on our Web site at: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.*[140]

By building on the existing reporting and submission infrastructure for LTCHs, such as the LTCH CARE Data Set, which will be used for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. We are proposing that the data collection would cover the period from October 1 through March 31 of each year, which corresponds with how NQF specifies this measure as well as other endorsed influenza vaccination measures. We refer readers to section VIII.D.6. of this preamble for more information on data collection and submission.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent FYs payment determinations.

(2) Proposed New LTCH Quality Measure #2 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) According to the CDC, pneumococcal disease kills more people in the United States each year than all other vaccine-preventable diseases combined.[141] In 2006, all possible pneumonia diagnoses (including viral, bacterial, and unspecified organisms) killed 55,477 people in the United States and were responsible for 1,232,999 hospital discharges.[142]

Older people and those with chronic health conditions are at higher risk for pneumococcal disease. In 2011 there were more than 40,000 cases of invasive pneumococcal disease in the United States, and approximately one-third of these occurred among persons ages 65 years and older.[143] A 2011 Medicare Payment Advisory Committee (MedPAC) report found that pneumonia is among the top 20 most common Medicare Severity Long-Term Care Diagnosis-Related Groups (MS–LTC–DRG).[144] In 2005, Medicare paid an average of $6,342 per hospital discharge for pneumonia-related short-stay hospitalizations.[145] Death related to pneumonia also affects the elderly at a higher rate. In 2004, 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these were amongst the elderly.[146]

Individuals in the LTCH setting are at especially high risk of contracting pneumonia as a complication of another medical condition, such as stroke, previous or recent surgery, or ventilation—all of which are conditions for which patients may spend some of their recovery time in the LTCH.[147,148,149]

Healthy People 2010 (Objective 14–29f) and Healthy People 2020 (Objective IID–13.3) each set a goal of 90 percent of adults vaccinated against pneumococcal disease in long-term care facilities.[150,151] However, estimated pneumococcal vaccination coverage remains below 50 percent in recommended high-risk groups.[152] No comparable information is currently available on patients in the LTCH setting.

In light of the previously described data which we believe reflects the significant impact pneumonia has on Medicare beneficiaries in the LTCH setting, we are proposing a quality measure on the pneumococcal vaccine. Specifically, we are proposing the measure Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) for application in the

[137] National Quality Forum (2008, December). National Voluntary Consensus Standards for Influenza and Pneumococcal Vaccinations. Available from *http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx.*

[138] The LTCH CARE Data Set, the proposed data collection instrument that would be used to submit data on this proposed measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

[139] Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from *https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp.*

[140] Centers for Medicare and Medicaid Services (2012, March). MDS 3.0 Quality Measures User's Manual. V5.0. pp. 15. Retrieved from: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.*

[141] Centers for Disease Control and Prevention. (2009, March). Pneumococcal polysaccharide vaccine: What you need to know. Retrieved from *http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf.*

[142] Centers for Disease Control and Prevention, National Center for Health Statistics. (various years 1988–2006). National Hospital Discharge Survey. Available from *http://www.cdc.gov/nchs/nhds/nhds_publications.htm#nhds.*

[143] Centers for Disease Control and Prevention. (2011). Pneumococcal diseases. In The Pink Book: epidemiology and prevention of vaccine preventable diseases (pp. 233–248). Retrieved from: *http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pneumo.pdf.*

[144] Medicare Payment Advisory Committee (MedPac). (2011, March) Long-term care hospital services. In Report to the Congress: Medicare payment Policy (pp 231–456). Washington, DC. Available from *http://www.medpac.gov/documents/Mar11_EntireReport.pdf.*

[145] Health Care Financing Review. Statistical supplement no. 293. (2007). Baltimore, MD: Centers for Medicare and Medicaid Services.

[146] Gorina Y, Kelly T, Lubitz J, *et al.* (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from *http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf.*

[147] Fagon JY, Chastre J, Hance AJ, Montravers P, Novara A, Gibert C. Nosocomial pneumonia in ventilated patients: a cohort study evaluating attributable mortality and hospital stay. Am J Med 1993;94:281–8.

[148] Gorina Y, Kelly T, Lubitz J, *et al.* (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from *http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf.*

[149] Centers for Disease Control and Prevention. (2011, June). Post-procedure pneumonia (PPP) event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/10pscPPPcurrent.pdf.*

[150] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (n.d.). Healthy People 2010 archive. Retrieved from *http://www.healthypeople.gov/2010/.*

[151] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from *http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23.*

[152] Centers for Disease Control and Prevention, National Center for Health Statistics. (various years 1988–2006). National Hospital Discharge Survey.

LTCHQR Program for the FY 2016 payment determination and subsequent fiscal year payment determinations. We recognize that the NQF has endorsed this measure for short stay nursing home residents but believe this measure is highly relevant to LTCHs as described previously. This measure reports the percentage of short-stay nursing home residents who were assessed and appropriately given the pneumococcal vaccine (PPV) during a 12-month reporting period. We are proposing this measure because, as stated previously, patients in LTCHs are at high risk of contracting pneumonia as a complication of another medical condition. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[153]

As indicated previously, section 1886(m)(5)(D)(ii) of the Act provides the Secretary with authority to adopt non-NQF-endorsed measures. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for pneumococcal vaccination in the LTCH setting. We are unaware of any other measures for pneumococcal vaccination in the LTCH setting that have been approved by voluntary consensus standards bodies and endorsed by NQF. We are proposing to adopt application of the Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) for application in the LTCHQR Program. This application is also consistent with the 2008 NQF steering committee recommendation that ''in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement.'' [154] Data for this measure are currently collected and reported as part of the Nursing Home Quality Initiative.

The specifications and data elements for this proposed measure are available in the MDS 3.0 QM User's Manual available on our Web site at: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf*.[155]

We are proposing that submission of data for this measure will be incorporated into the existing data collection and submission framework for LTCHs that we adopted for the FY 2014 payment determinations.[156] We intend to revise the LTCH CARE data set to include new items which assess patient's pneumococcal vaccination status should this proposed measure be adopted. These items will be based on the items from the Minimum Data Set (MDS) 3.0 items.[157]

By building on the existing LTCH reporting and submission infrastructure, such as the LTCH CARE data set, which will be used by LTCHs for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For additional information of data collection and submission, we refer readers to section VIII.D.6. of this preamble. We invite public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

(3) Proposed New LTCH Quality Measure #3 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)

As previously noted, influenza virus infections are a major source of preventable mortality in the Medicare population. Between 1976 and 2007, influenza virus infections resulted in an average of 23,607 influenza-related deaths with a yearly range of 3,349 to 48,615 deaths, with approximately 90 percent of these deaths occurring among persons aged 65 or older.[158] Health care personnel are at risk for both acquiring influenza from patients and exposing it to patients, and health care personnel often come to work when ill.[159] One early report of health care personnel influenza infections during the 2009 H1N1 influenza pandemic estimated 50 percent of infected health care personnel had contracted the influenza virus from patients or coworkers in the healthcare setting.[160]

The Advisory Committee on Immunization Practices (ACIP) recommends that all health care personnel get an influenza vaccine every year to protect themselves and patients.[161] Even though levels of influenza vaccination among health care personnel have slowly increased over the past 10 years, less than 50 percent of health care personnel each year received the influenza vaccination until the 2009–2010 season, when an estimated 62 percent of health care personnel got a seasonal influenza vaccination. In the 2010–2011 season, 63.5 percent of health care personnel reported influenza vaccination. Healthy People 2020 (Objective IID–12.9) set a goal of 90 percent for health care personnel influenza vaccination.[162] It is important to measure influenza vaccination of health care personnel every season to track progress toward this objective and to make sure that health care personnel and their patients are protected from influenza.[163] Increased influenza vaccination coverage among health care personnel is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, aligning with the National Quality Strategy's aims of better care and healthy people/communities.

In light of the previously described data which we believe reflects the significant impact influenza has on Medicare beneficiaries in the LTCH setting, we are proposing to adopt an influenza measure. Specifically, we are

[153] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

[154] National Quality Forum (2008, December) National Voluntary Consensus Standards for influenza and pneumococcal vaccinations rretrieved from *http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx*.

[155] Centers for Medicare and Medicaid Services (2012, March). MDS 3.0 Quality Measures User's Manual. V5.0. pp. 15. Retrieved from: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf*.

[156] The LTCH CARE Data Set, the proposed data collection instrument that would be used to submit data on this proposed measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

[157] Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from *https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp*.

[158] Thompson MG, Shay DK, Zhou H, *et al.* Estimates of deaths associated with seasonal influenza—United States, 1976–2007. MMWR Morb Mortal Wkly Rep. 59(33):1057–1062.

[159] Wilde JA, McMillan JA, Serwint J, *et al.* Effectiveness of influenza vaccine in healthcare professionals: A randomized trial. JAMA. 1999; 281: 908–913.

[160] Harriman K, Rosenberg J, Robinson S, *et al.* Novel influenza A (H1N1) virus infections among health-care personnel—United States, April–May 2009. MMWR Morb Mortal Wkly Rep. 2009; 58(23): 641–645.

[161] Fiore AE, Uyeki TM, Broder K, *et al.* Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR Recomm Rep. 2010. 59(08): 1–62.

[162] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from *http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23*.

[163] Lindley MC, Zhang J, Euler G. Health care personnel flu vaccination (2011, November). Retrieved from *http://www.cdc.gov/flu/pdf/professionals/vaccination/1112-healthcare.pdf*.

proposing to adopt the CDC-developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the FY 2016 payment determination and subsequent fiscal year payment determinations. We also note that this measure is undergoing NQF review as part of measure maintenance (*http://www.qualityforum.org/Projects/n-r/Population_Health_Prevention/Population_Health__Prevention_Endorsement_Maintenance_-_Phase_1.aspx#t=2&s=&p=3%7C*). We are proposing to this measure because, as stated previously, it aligns with national initiatives. It is also already endorsed for the LTCH care setting. This measure has been finalized for reporting in the Hospital IQR Program and the Ambulatory Surgical Centers Quality Reporting Program. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[164]

This measure reports on the percentage of health care personnel who receive the influenza vaccination. Health care personnel refers to all paid and unpaid persons working in health care settings, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from health care personnel. This measure is applicable to LTCHs (we refer readers to the CDC/NHSN Manual, Healthcare Personnel Safety Component Protocol Module, Influenza Vaccination and Exposure Management Modules, which is available at the CDC Web site at: *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf for measure specifications and additional details.*

We are proposing that data collection for this measure would be through the CDC/NHSN (*http://www.cdc.gov/nhsn/*). It is a secure Internet based system maintained by CDC, and can be utilized by all types of health care facilities in the United States, including LTCHs. NHSN collects data via a Web-based tool hosted by the CDC and available at: *http://www.cdc.nhsn.* For FY 2106 and subsequent future fiscal year payment determinations, we are proposing that the data collection would cover the period from October 1 through March 31 of each year, which corresponds with how NQF specifies this measure as well as other endorsed influenza vaccination measures.

CDC/NHSN is also the proposed data collection and submission framework for reporting on CAUTI and CLABSI measures for the FY 2015 payment determination.[165] Details related to the procedures for using the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at *http://www.cdc.gov/nhsn/hps_fluVaccExpos.html*. By building on the CDC/NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For additional information on data collection and submission, we refer readers to section VIII.D.6. of this preamble.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

(4) Proposed New LTCH Quality Measure #4 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Ventilator Bundle (NQF #0302)

In 2009, the most frequently occurring diagnosis in the LTCHs was MS–LTC–DRG 207 (Respiratory Diagnosis with Ventilator Support for 96 or more Hours).[166] Ventilator-Associated Pneumonia (VAP) is a costly, often deadly infection. A systematic review of VAP found: (1) Between 10 percent and 20 percent of patients receiving greater than 48 hours of ventilation will develop VAP; (2) ill patients who develop VAP are twice as likely to die as compared with similar patients without VAP; (3) patients with VAP have significantly longer lengths of stay; and (4) patients who have VAP incur over $10,000 in additional hospital costs.[167]

In light of the previously described data on VAP which we believe reflects the significant impact VAP has on Medicare beneficiaries, our measure development contractor introduced the VAP measure for discussion at a technical expert panel convened by it on January 31, 2011. The TEP identified VAP as important for the LTCH setting due to the high percentage of patients on ventilators. However, the panel noted concerns about measuring the rate of VAP due to lack of a consistent definition, concerns of inter-rater reliability, subjective interpretation of VAP, and variability in diagnosing VAP.

Our measure development contractor reviewed this concept again and introduced the Ventilator Bundle (NQF #0302) developed by Institute of Healthcare Improvement for discussion to address some the concerns noted previously at a July 7, 2011 TEP meeting. This comprehensive ventilator care-bundle process measure is designed to facilitate protocols such as weaning, and mitigate ventilator-related infections, such as VAP. The NQF-endorsed ventilator bundle measure consists of four components: (1) Head of the bed elevation ≥30°; (2) daily sedation interruption and assessment of readiness to wean; (3) peptic ulcer disease (PUD) prophylaxis; and (4) deep vein thrombosis (DVT) prophylaxis, The measure steward, the Institute for Healthcare Improvement, also recommends a fifth element be added to the ventilator bundle-process measure: daily oral care with Chlorhexidine (*http://www.ihi.org/offerings/MembershipsNetworks/MentorHospitalRegistry/Pages/VentilatorBundle.aspx*). A meta-analysis of oral decontamination found a statistically significant reduction in VAP with use of antiseptic oral decontamination, which supports such an addition.[168]

We recognize that the Ventilator Bundle (NQF #0302) measure is currently endorsed for ICU patients in the acute care hospital setting; however, we believe this measure is highly relevant for the LTCH setting because ventilator patients are a large segment of the LTCH patient population and a process measure to reduce VAP is important and relevant for the LTCH setting. In addition, the MAP supports the direction of this measure, and believes it is an important aspect of care in LTCHs, and has identified it as a high

[164] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

[165] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment, Final Rule. Federal Register (August 18, 2011; 76 FR 51745–51846). Web. *http://www.gpo.gov/fdsys/pkg/FR-2011-08-18/pdf/2011-19719.pdf.*

[166] Medicare Payment Advisory Commission (MedPAC). (2011, March). Long-term care hospital services. In Report to the Congress: Medicare payment policy (pp. 231–256). Washington, DC: Retrieved from *http://medpac.gov/documents/Mar11_EntireReport.pdf.*

[167] Safdar, N., Dezfulian, C., Collard, H., Saint, S. ''Clinical and Economic Consequences of Ventilator Associated Pneumonia''. *Critical Care Medicine.* 2005: 33(10): 2184–93.

[168] Chan, E., Ruest, A., Meade, M., Cook, D. ''Oral decontamination for prevention of pneumonia in mechanically ventilated adults: systematic review and meta-analysis''. *BMJ.* 2007; 334: 889.

priority.[169] Further, we are proposing this measure because it supports the National Quality Strategy by supporting better and safer care that prevents infection among patients at risk for VAP. Therefore, for the above-described reasons, we are proposing Ventilator Bundle NQF #0302 for application in the LTCH setting.

As indicated previously, section 1886(m)(5)(D)(ii) of the Act provides the Secretary with authority to adopt non-NQF-endorsed measures. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for the ventilator bundle in the LTCH setting. We are unaware of any other measures for the ventilator bundle in the LTCH setting that have been approved by voluntary consensus standards bodies and endorsed by NQF. We are proposing to adopt the Ventilator bundle for application in the LTCHQR Program. Therefore, under the authority of section 1886(m)(5)(D)(ii) of the Act, we are proposing to use the Ventilator Bundle (NQF #0302) measure for application in the FY 2016 LTCHQR Program payment determination and subsequent fiscal year payment determinations.

We further note that this measure is undergoing endorsement maintenance review at the NQF under the Patient Safety Measures-Complications Project (*http://www.qualityforum.org/Projects/n-r/Patient_Safety_Measures_Complications/Patient_Safety_Measures_Complications.aspx#t=2&s=&p=*).

We are proposing that data collection and submission of this measure will be through the LTCH CARE Data Set. We intend to revise the LTCH CARE Data Set to include new items on LTCHs' compliance with each element of the ventilator bundle measure if the measure is finalized. These items would be based on the data elements of the ventilator bundle in use within hospitals implementing the ventilator bundle process measure (NQF #0302). The specifications and data elements for this proposed measure are available at NQF Web site at: *http://www.qualityforum.org/QPS/302*.

By building on the existing LTCH reporting and submission infrastructure, such as the LTCH CARE data set, which will be used by LTCHs for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For additional information of data collection and submission, we refer readers to section VIII.D.6. of this preamble.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

(5) Proposed New LTCH Quality Measure #5 for the FY 2016 Payment Determination and Subsequent Fiscal Year Payment Determinations: Restraint Rate per 1,000 Patient Days

Restraints are used to control behavior for people who exhibit disruptive, aggressive, or dangerous behavior in health care settings.[170,171,172,173] The negative outcomes of restraints may include strangulation, loss of muscle tone, decreased bone density (with greater susceptibility for fractures), pressure sores, increased infections, decreased mobility, depression, agitation, loss of dignity, social isolation, incontinence, constipation, functional decline, abnormal changes in body chemistry and muscular function, and in some cases, patient death.[174,175,176,177,178,179,180,181,182,183] The use of physical restraints also often constitutes a disproportionate infringement on an individuals' autonomy.[184,185]

Research suggests that other clinical interventions are more effective than restraints in preventing injuries from falls. Interventions involving physiologic care, psychosocial care and environmental manipulation, have been shown to be more effective than restraints, generally without increasing staff time or overall cost of treatment.[186,187,188,189,190,191]

The principle of freedom from physical or pharmacological restraint is generally understood and accepted by professional and academic organizations. Groups such as the National Citizens' Coalition for Nursing Home Reform (NCCNHR), the Alzheimer's Association, and the American Physical Therapy Association, as well as numerous nursing homes and academic medical research institutions are involved in limiting the use of restraints. The Untie the Elderly campaign has been working since 1989 to raise public awareness of restraint abuse,[192] and the Advancing Excellence in America's Nursing Homes has recently embedded reduction of the use of restraints in nursing homes as part of an overall goal to increase resident mobility to help nursing home staff address mobility issues including the use of restraints, walking, range of motion, transfer, and prevention of falls.[193]

[169] National Quality Forum (2012)Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

[170] Sullivan-Marx E, Strumpf N, Evans L, *et al.* Initiation of physical restraint in nursing home residents following restraint reduction efforts. Res Nurs Health. 1999;22:369–79.

[171] Capezuti E, Evans L, Strumpf N, *et al.* Physical restraint use and falls in nursing home residents. J Am Geriatr Soc. 1996;44:627–33.

[172] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139–70.

[173] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30–37.

[174] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139–70.

[175] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773–5.

[176] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56–61.

[177] Evans L, Strumpf N, Allen-Taylor S, *et al.* A clinical trial to reduce restraints in nursing homes. J Am Geriatr Soc. 1997;45(6):675–81.

[178] Capezuti E, Maislin G, Strumpf N, *et al.* Side rail use and bed-related fall outcomes among nursing home residents. J Am Geriatr Soc. 2002;50(1):90–6.

[179] Parker K, Miles S. Deaths caused by bed rails. J Am Geriatr Soc. 1997;45:797–802.

[180] Feinsod FM, Moore M, Levenson S. Eliminating full-length bed rails from long term care facilities. Nurs Home Med. 1997;5:257–63.

[181] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30–37.

[182] Mohoney JE. Immobility and falls. Clin Geriatr Med. 1998. 14 (4): 699–726.

[183] Inouye SK, Wagner DR, Acompara D, *et al.* A predictive index for functional decline in hospitalized elderly medical patients. J Gen Intern Med. 1993; 8(12):645–652.

[184] Gastmans C, Milison K. Use of physical restraint in nursing homes: clinical-ethical considerations. J Med Ethics. 2006;32:148–52.

[185] McBrian B. Exercising restraint: clinical, legal and ethical considerations for the patient with Alzheimers's disease. Accide emeg nurs. 2997 Apr 15 (2):94–100.

[186] Capezuti E, Evans L, Strumpf N, *et al.* Physical restraint use and falls in nursing home residents. J Am Geriatr Soc. 1996;44:627–33.

[187] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139–70.

[188] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30–37.

[189] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773–5.

[190] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56–61.

[191] Evans L, Strumpf N, Allen-Taylor S, *et al.* A clinical trial to reduce restraints in nursing homes. J Am Geriatr S c. 1997;45(6):675–81.

[192] Untie the Elderly Web site; accessed January 21, 2010, at *http://ute.kendaloutreach.org/Default.aspx*.

[193] Advancing Excellence in America's Nursing Homes Web site; accessed March 24, 2012, at *http://*

Continued

CMS and other Federal agencies have issued several regulations regarding restraint use in healthcare settings. In the 2006 Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights final rule (71 FR 71378 through 71428), we stated that the use of restraints or seclusion ''may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others'' (71 FR 71382).[194] Additionally, in 2010, the Food and Drug Administration's Hospital Bed Safety workgroup released clinical guidance for limiting the use of bed rails, reflecting concern about the safety of restraints.[195] To better align with our guidelines, The Joint Commission updated its standards to establish guidelines limiting the use of restraints and seclusion, and clarifying the documentation and usage protocols for hospitals in 2009.[196]

Recognizing the importance of a restraint rate measure, our measure development contractor convened a technical expert panel to review restraint measures for potential use in the LTCHQR. The TEP reviewed several NQF-endorsed measures for restraint use, including Restraint Prevalence (vest and limb only) (NQF #0203) endorsed for short-term acute care hospitals, HBIPS–2 Hours of Physical Restraint Use (NQF #0640) endorsed for inpatient psychiatric facilities, HBIPS–3 Hours of Seclusion Use (NQF #0641) endorsed for inpatient psychiatric facilities, and Percent of Residents who were Physically Restrained (Long-Stay) (NQF # 0687) endorsed for residents who have been in the nursing home for over 100 days. We note the measures are NQF endorsed, although not for the LTCH setting. We submitted NQF #0687 mentioned above to the MAP for consideration. While the MAP supported the direction of this measure, it also advised the measure needed to tested in and specified for the LTCH setting. Subsequently, we also determined that all four of the above-referenced NQF measures were limited in their potential to produce a meaningful measurement in the LTCH setting since these measures have look back and monitoring periods that are problematic for the LTCH setting.

Upon further investigation, we identified the ''Restraint Rate per 1,000 Patient Days'' measure which was developed by the National Association of Long Term Hospitals (NALTH) and is a non-core measure for The Joint Commission ORYX Initiative. This measure is not NQF endorsed but it is currently specified for and is in use by some LTCHs who submit data for this measure to the NALTH Health Information System. Thus, this measure is specified for and in use for the LTCH setting, thereby, this measure is a feasible and practical measure for LTCH setting. Therefore we believe it addresses the concerns raised by MAP with respect to NQF #0687 which is the need for specification and use in the LTCH setting

After review of the previously referenced NQF-endorsed restraint measures, we are proposing the Restraint Rate per 1,000 Patient Days measure for the FY 2016 LTCHQR Program payment determination and subsequent fiscal year payment determinations under the authority in section 1886(m)(5)(D)(ii) of the Act. We are proposing to use the exception authority because there are no NQF endorsed measures on restraints for the LTCH setting. Further, as explained previously, we have given due consideration to the existing NQF measures on restraints (although not endorsed for the LTCH setting) and we believe they are not appropriate for the LTCHQR. We are proposing this measure because we believe it is a relevant, scientifically sound, valid, and an important measure which is also feasible for data collection in the LTCH setting compared to the existing NQF-endorsed restraint measures previously discussed. For this proposed measure, the measure specifications will be made available on the LTCHQR Program Web site at *http://www.cms.gov/LTCH-Quality-Reporting/*.

We are proposing that the data collection and submission of this measure will be through the LTCH CARE Data Set. This is the same data collection and submission framework which we would use to support providers for reporting on the Percent of Residents with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) measure.[197]

By building on existing data reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For more information on data collection and submission, we refer readers to section VIII.D.6. of this preamble.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal year payment determinations.

5. Proposed Timeline for Data Submission Under the LTCHQR Program for the FY 2015 Payment Determination

For the FY 2015 payment determination, we are proposing to require data submission on LTCH discharges occurring from January 1, 2013 through December 31, 2013 (CY 2013). LTCHs would follow the proposed deadlines presented in the table below to complete submission of data for each quarter for each proposed measure for the FY 2015 payment determination. For each quarter outlined in the table below during which LTCHs are required to collect data, we are proposing a final submission deadline occurring approximately 135 days after the end of each quarter by which all data collected during that quarter must be submitted to CMS. We believe that this is a reasonable amount of time to allow providers to submit data and make any necessary corrections.

www.nhqualitycampaign.org/files/NewGoals_030612.pdf and Physical Restraints Tracking Tool v1.1 (December, 2011) accessible through *http://www.nhqualitycampaign.org/files/campaign_updates.htm#cms*.

[194] CMS Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights final rule. 2006. Available from *https://www.cms.gov/CFCsAndCoPs/downloads/finalpatientrightsrule.pdf*.

[195] FDA Hospital Bed Safety Workgroup; accessed January 25, 2010. Available from: *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/MedicalToolsandSupplies/HospitalBeds/default.htm*.

[196] The Joint Commission. Restraint/Seclusion for hospitals that use the joint commission for deemed status purposes. 2009. Available from: *http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=260&ProgramId=1*.

[197] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2015 PAYMENT DETERMINATION

Data collection timeframe: CY 2013	Proposed final submission deadline for data related to the LTCH Quality Reporting Program FY 2015 payment determination
Q1 (January–March 2013)	August 15, 2013.
Q2 (April–June 2013)	November 15, 2013.
Q3 (July–September 2013)	February 15, 2014.
Q4 (October–December 2013)	May 15, 2014.

We are inviting public comment on this proposed submission timeline for the FY 2015 payment determination.

6. Proposed Timeline for Data Submission Under the LTCHQR Program for the FY 2016 Payment Determination

For the FY 2016 payment determination, we are proposing to require data submission on LTCH discharges occurring from January 1, 2014 through December 31, 2014 (CY 2014). We are proposing this timeframe because we believe this would provide sufficient time for LTCHs and CMS to put processes and procedures in place to meet the additional quality reporting requirements. LTCHs would follow the proposed deadlines presented in the table below to complete submission of data for each quarter. For each quarter outlined in the table below during which LTCHs are required to collect data, we are proposing a final deadline occurring approximately 45 days after the end of each quarter by which all data collected during that quarter must be submitted to CMS. We believe that this is a reasonable amount of time to allow providers to submit data and make any necessary corrections. We are also proposing that similar calendar year collection and submission deadlines would apply to future years payment determinations.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION AND SUBSEQUENT FISCAL YEAR PAYMENT DETERMINATIONS

Data collection timeframe: CY 2014	Final submission deadlines for the LTCHQR Program FY 2016 payment determination
Q1 (January–March 2014)	May 15, 2014.
Q2 (April–June 2014)	August 15, 2014.
Q3 (July–September 2014)	November 15, 2014.
Q4 (October–December 2014)	February 15, 2015.

We are inviting public comment on this proposed submission timeline for FY 2016 Payment Determination and future year payment determinations.

7. Proposed Public Display of Data Quality Measures

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs under section 1886(m)(5)(C) of the Act available to the public. In addition, section 1886(m)(5)(E) of the Act requires that such procedures shall ensure that a LTCH has the opportunity to review the data that is to be made public with respect to its facility, prior to such data being made public. In addition, the statute requires that the Secretary shall report quality measures that relate to services furnished in LTCHs on our Internet Web site. Therefore, the Secretary will publicly report quality measure data that is reported under the LTCHQR Program. Currently, we are not proposing procedures or timelines for public reporting of LTCHQR Program data.

E. Proposed Quality Reporting Requirements for Ambulatory Surgical Centers (ASCs)

1. Background

Section 109(b) of the Medicare Improvements and Extension Act of 2006 under Division B, Title I of the Tax Relief and Health Care Act of 2006, Public Law 109–432 (MIEA–TRHCA) amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit ''data required to be submitted on measures selected under this paragraph with respect to a year'' to the Secretary in accordance with this paragraph will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year.

Subparagraph (B) of paragraph (7) states ''[e]xcept as the Secretary may otherwise provide,'' the provisions of subparagraphs (B) through (E) of paragraph (17) of section 1833(t) of the Act, which contain requirements for quality reporting for hospital outpatient services, ''shall apply with respect to services of [ASCs] under this paragraph in a similar manner to the manner in which they apply under such paragraph'' and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Pertinent to this proposed rule are subparagraphs (B) and (E) of section 1833(t)(17) of the Act. Subparagraph (B) of section 1833(t)(17)

of the Act requires subsection (d) hospitals to ''submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.'' Subparagraph (E) of section 1833(t)(17) of the Act requires the Secretary to ''establish procedures for making data submitted under this paragraph available to the public.'' Further, these procedures shall ensure that hospitals have the opportunity to review the data before these data are made public. Additionally, the Secretary must ''report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals'' on CMS' Internet Web site.

Thus, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require that ASCs submit quality data in a form and manner, and at a time, that the Secretary specifies. Pertinent to this proposed rule, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require the Secretary to establish procedures for making data submitted available to the public and to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and cost of care that relate to services furnished in ASCs on CMS's Internet Web site. Subsection (i)(7)(B) of section 1833 of the Act also specifies that these provisions apply except as the Secretary may otherwise provide.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination (76 FR 74492 through 74517). We adopted claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012. For the CY 2015 payment determination, we adopted the same claims-based measures as adopted for the CY 2014 payment determination and two structural measures. We did not specify the data collection period for the claims-based measures for the CY 2015 payment determination, but specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012 using an online measure submission Web page available at: *http://www.QualityNet.org*. For the CY 2016 payment determination, we adopted the same claims-based and structural measures as adopted for the CY 2015 payment determination and one process of care measure. We did not specify the data collection period for the claims-based or structural measures, but specified that data collection for the process of care measure would be via the National Healthcare Safety Network beginning on October 1, 2014 and continuing through March 31, 2015.

In the CY 2012 OPPS/ASC final rule with comment period, we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule rather than in the CY 2013 OPPS/ASC proposed rule (76 FR 74515), because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to be finalized earlier and prior to data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012.

Below we are issuing proposals for administrative requirements, data completeness requirements, extraordinary circumstance waiver or extension requests, and a reconsideration process. As discussed below, we are not proposing to validate claims-based and structural measures. Further, we intend to address appeals of reconsideration decisions in a future rulemaking. To be eligible to receive the full annual increase, we are proposing that ASCs must comply with the requirements specified below for the respective payment determination year.

We invite public comment on these proposals.

2. Proposed Requirements for Reporting of ASC Quality Data

a. Proposed Administrative Requirements

(1) Proposals Regarding QualityNet Account and Administrator for the CYs 2014 and 2015 Payment Determinations

A QualityNet account is required to submit quality measure data to the QualityNet Web site and, in accordance with CMS policy, a QualityNet administrator is necessary to set-up a user account for the purpose of submitting this information to the QualityNet Web site. The main purpose of a QualityNet administrator is to serve as a point of contact for security purposes for quality reporting programs. We believe from our experience that a QualityNet administrator typically fulfills a variety of tasks related to quality reporting, such as creating, approving, editing, and terminating QualityNet user accounts within an organization, and monitoring QualityNet usage to maintain proper security and confidentiality measures. Thus, we highly recommend that ASCs have and maintain a QualityNet administrator. However, we are not proposing that ASCs be required to do so for the CY 2014 payment determination because ASCs are not required to submit data to the quality data warehouse for the CY 2014 payment determination (76 FR 74504) and we do not want to unduly burden ASCs by requiring ASCs to have a QualityNet administrator. We note that a QualityNet account is not necessary to access information that is posted to the QualityNet Web site, such as specifications manuals and educational materials.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74509), for the CY 2015 payment determination, we require ASCs to submit structural measure data to the QualityNet Web page. To enter these data into the CMS data system, we are proposing that ASCs will need to identify and register a QualityNet administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. Because submission of structural measure data is not required until the July 1, 2013 to August 15, 2013 time period, we are proposing that ASCs would be required to have a QualityNet administrator at the time facilities submit structural measure data in 2013 for the CY 2015 payment determination, which is no later than August 15, 2013. ASCs may have a QualityNet administrator prior to this date, but we are not proposing that ASCs be required to do so.

We note that there are necessary mailing and processing procedures for having a QualityNet administrator assigned by CMS separate from completion of the forms by the ASC that can require significant time to complete and we strongly caution ASCs to not wait until the deadline to apply; instead, we recommend allowing a minimum of 2 weeks, while strongly suggesting allowing additional time prior to the deadline to submit required documentation in case of unforeseen issues. Because ASCs will need a QualityNet administrator only to have the ability to set up a user account for the purpose of submitting structural measure data once a year, we are proposing that ASCs would not be required to maintain a QualityNet administrator after the entry of the structural measure data in 2013 for the CY 2015 payment determination. Although we highly recommend that ASCs have and maintain a QualityNet administrator, we believe that requiring

an ASC to maintain a QualityNet administrator throughout the year would increase the burden on ASCs.

As a commenter noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), QualityNet accounts are automatically deactivated after a 120-day period of inactivity per CMS security policy. If an account is deactivated due to inactivity, it can be reactivated by contacting the QualityNet Help Desk; contact information for the QualityNet Help Desk is located on the QualityNet Web site.

(2) Proposals Regarding Participation Status for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We finalized in the CY 2012 OPPS/ASC final rule with comment period a policy to consider an ASC as participating in the ASC Quality Reporting Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the program on their CY 2012 claims relating to the finalized measures (76 FR 74516).

We are proposing that once an ASC submits any quality measure data, it would be considered as participating in the ASC Quality Reporting Program. Further, we are proposing that, once an ASC submits any quality measure data and is considered to be participating in the program, an ASC would continue to be considered participating in the program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the program by indicating on a participation form that it is withdrawing, as discussed below. For example, if an ASC includes any QDCs on its claims for the CY 2014 payment determination, it would be considered participating in the ASC Quality Reporting Program for the CY 2014 payment determination and for every subsequent payment determination unless the ASC withdraws. Likewise, if an ASC did not submit any QDCs for the CY 2014 payment determination, but submitted quality measure data for the CY 2015 payment determination, the ASC would be considered participating in the ASC Quality Reporting Program starting with the CY 2015 payment determination and continuing for subsequent payment determinations unless the ASC withdraws from the program.

We considered whether to propose that an ASC be required to complete and submit a notice of participation form for the CY 2015 payment determination or subsequent payment determination years to indicate that the ASC is participating in the program as we require for hospitals, but decided against this proposal because we were concerned about the burden on ASCs. We believe these proposals will reduce burden on ASCs while accomplishing the purpose of notifying CMS of an ASC's participation in the ASC Quality Reporting Program.

We are proposing that any and all quality measure data submitted by the ASC while participating in the ASC Quality Reporting Program could be made publicly available. This policy would allow us to provide information on the quality of care provided to Medicare beneficiaries which promotes transparency.

We are proposing that once an ASC submits quality measure data indicating its participation in the ASC Quality Reporting Program an ASC must complete and submit an online participation form indicating withdrawal to withdraw from the program. This form would be located on the QualityNet Web site starting in July 2013. We are proposing that an ASC would indicate on the form the initial payment determination year to which the withdrawal applies. We are proposing a different process for ASCs to withdraw from participation than the process we are proposing for an ASC to participate in the ASC Quality Reporting Program because of the payment implications of withdrawal. We are proposing that, in withdrawing from the program, the ASC would incur a 2.0 percentage point reduction in its annual payment update for that payment determination year and any subsequent payment determination year(s) in which it is withdrawn.

We will not make quality measure data publicly available for that payment determination year and any subsequent payment determination year(s) for which the ASC is withdrawn from the program.

We are proposing that an ASC would continue to be deemed withdrawn unless the ASC starts submitting quality measure data again. Once an ASC starts submitting quality measure data, the ASC would be considered participating unless the ASC withdraws, as discussed above. Again, we believe that these proposals would reduce the burden on ASCs of having to notify CMS as to when they are participating.

We are proposing that an ASC can withdraw from the program at any time up to August 31, 2013 for the CY 2014 payment determination; we anticipate that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting CY 2014 payment are made. We are proposing that an ASC can withdraw from the program at any time up to August 31, 2014 for the CY 2015 payment determination. We will propose withdrawal dates for later payment determinations in future rulemakings.

We are proposing that these administrative requirements would apply to all ASCs designated as open in the CASPER system before January 1, 2012 for the CY 2014 payment determination. Since ASCs are not required to include QDCs on claims until October 2012 for the CY 2014 payment determination, an ASC designated as open in the CASPER system before January 1, 2012 would be operating for at least 10 months before having to report any data. We believe this would be a sufficient amount of time for ASCs to be established to report quality data for the CY 2014 payment determination.

For the CY 2015 payment determination, we are proposing that these administrative requirements would apply to all ASCs designated as open in the CASPER system for at least four months prior to January 1, 2013. We believe that this date and length of operations experience would provide new ASCs sufficient time before having to meet quality data reporting requirements after the program's initial implementation year.

We invite public comment on these proposals relating to administrative requirements.

b. Proposals Regarding Form, Manner, and Timing for Claims-Based Measures for CYs 2014 and 2015 Payment Determinations

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims based measures for the CYs 2014 and 2015 payment determinations (76 FR 74504 through 74509). We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). Further, we finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. We did not finalize a date by which claims would be processed to be considered for CY 2014 payment determinations.

We are now proposing that claims for services furnished between October 1, 2012 and December 31, 2012 would have to be paid by the administrative contractor by April 30, 2013 to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date would allow ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

We did not finalize a data collection and processing period for the CY 2015 payment determination, but intend to do so in the CY 2013 OPPS/ASC proposed rule.

(2) Proposed Minimum Threshold for Claims-Based Measures Using QDCs

In the CY 2012 OPPS/ASC final rule with comment period, we finalized that data completeness for claims-based measures would be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claim. In other words, the numerator will be the total number of claims meeting measure specifications that have QDCs and the denominator will be the total number of claims meeting measure specifications. We stated our intent to propose how we would assess data completeness for claims-based measures in this proposed rule (76 FR 74516). For the initial reporting years, we believe that a lower threshold for data completeness should be established for data collection because ASCs are not familiar with how to report quality data under the ASC Quality Reporting Program, and because many ASCs are relatively small and they may need more time to set up their reporting systems. For the CYs 2014 and 2015 payment determinations, we are proposing that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe 50 percent is a reasonable minimum threshold based upon the considerations discussed above for the initial implementation years of the ASC Quality Reporting Program. We intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for this quality data reporting program.

As stated in CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claim forms, the Form CMS–1500s submitted for payment, to submit the applicable quality data. A listing of the codes with long and short descriptors is available in transmittal 2425, Change Request 7754 released March 16, 2012 (*http://www.cms.gov/transmittals/downloads/R2425CP.pdf*). Details on how to use these codes for submitting numerators and denominator information will be available in the ASC Quality Reporting Program Specifications Manual located on our Web site (*http://www.cms.hhs.gov*) beginning in April 2012.

We invite public comment on these proposals relating to form, manner, and timing for claims-based measures.

c. ASC Quality Reporting Program Validation of Claims-Based and Structural Measures

We received comments on the CY 2012 OPPS/ASC proposed rule requesting that rules for data validation be adopted as soon as possible (76 FR 74515). We noted that claims-based and structural measures historically have not been validated through independent medical record review in our quality reporting programs for either hospitals or physicians due to the lack of relevant information in medical record documentation for specific data elements of the measures, such as use of a safe surgery checklist. Thus, consistent with other CMS quality reporting programs, we are not proposing to validate claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) and structural measures for the ASC Quality Reporting Program.

3. Proposed Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Payment Determination Years

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. Therefore, we are proposing procedures for extraordinary circumstance extension or waiver requests for the submission of information, including but not limited to, QDCs submitted on claims, required under the ASC Quality Reporting Program.

In the event of extraordinary circumstances, such as a natural disaster, that is not within the control of the ASC, we are proposing to adopt a process for an extension or waiver for submitting information for meeting program requirements that is similar to the one adopted for the Hospital OQR Program because this process has been effective for hospitals, and we believe such a process also would be effective for ASCs. We are proposing that an ASC would complete a request form that would be made available on the QualityNet Web site and submit the request to CMS. We are proposing that the following information must be noted on the form:

- ASC CMS Certification Number (CCN) and related National Provider Identifier(s) [NPI(s)];
- ASC Name;
- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- ASC's reason for requesting an extension or waiver;
- Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the ASC would be able to submit required ASC Quality Reporting Program information, and a reasonable basis for the proposed date.

We are proposing that the request form would be signed by a person who has authority to sign on behalf of the ASC and a request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, we are proposing that CMS would—

(a) Provide a written acknowledgement using the contact information provided in the request, notifying the ASC contact that the ASC's request has been received;

(b) Provide a formal response to the ASC contact using the contact information provided in the request notifying the ASC of our decision; and

(c) Complete its review of any request and communicate its response within 90 days following CMS's receipt of such a request.

We are proposing that we would also have discretion to grant waivers or extensions to ASCs that have not been formally requested by them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. We are proposing that,

if we make the determination to grant a waiver or extension to ASCs in a region or locale, we would communicate this decision to ASCs and vendors through routine communication channels, including, but not limited to, e-mails and notices on the QualityNet Web site.

We invite public comment on this proposed process for granting extraordinary circumstances extensions or waivers for the submission of information for the ASC Quality Reporting Program.

4. Proposed ASC Quality Reporting Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We have established similar processes by which participating hospitals can submit requests for reconsideration of quality reporting program payment determinations for the Hospital IQR Program and the Hospital OQR Program. We believe these reconsideration processes have been effective in the hospital quality reporting programs and such a process would be effective for ASC quality reporting. Therefore, we are proposing to implement a reconsideration process for the ASC Quality Reporting Program modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs.

We are proposing that an ASC seeking reconsideration would be required to submit to CMS a Reconsideration Request form that would be made available on the QualityNet Web site. We are proposing that the request form would be signed by a person who has authority to sign on behalf of the ASC and that this form must be submitted by March 17 of the affected payment year (for example, for the CY 2014 payment determination, the request must be submitted by March 17, 2014).

We are proposing to use a deadline of March 17 to provide sufficient time for an ASC to see the effects of a payment reduction on its January claims. Administrative contractors have 30 days to process (pay or deny) clean claims. Administrative contractors have 45 days to process claims other than clean ones (that is, claims that require the contractor to query for more information, look at medical documentation, among others) (Claims Processing Manual, Chapter 1, Section 80; sections 1869(a)(2), 1816(c)(2) and 1842(c)(2) of the Act). We are proposing March 17 because this date is 45 days after an ASC would have had the opportunity to provide one full month of services (that is, March 17 is 45 days after January 31).

This Reconsideration Request form would contain the following information:

- ASC CCN and related NPI(s);
- ASC Name;
- CMS-identified reason for not meeting the affected payment year's ASC Quality Reporting Program requirements as provided in any CMS notification to the ASC;
- ASC basis for requesting reconsideration. We are proposing that the ASC must identify the ASC's specific reason(s) for believing it met the affected payment year's ASC Quality Reporting Program requirements and should receive the full ASC annual payment update;
- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include physical address, not just a post office box); and
- A copy of all materials that the ASC submitted to comply with the affected payment year's ASC Quality Reporting Program requirements. With regard to information submitted on claims, we are proposing ASCs would not be required to submit copies of all submitted claims, but instead would focus on the specific claims at issue. Thus, ASCs would submit relevant information, which could include copies of the actual claims at issue.

Following receipt of a request for reconsideration, we are proposing that we would:

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the ASC contact notifying the ASC that the ASC's request has been received; and
- Provide a formal response to the ASC contact, using the contact information provided in the reconsideration request, notifying the ASC of the outcome of the reconsideration process.

We intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration.

We intend to issue proposals regarding appeals of ASC Quality Reporting Program reconsideration decisions in a future rulemaking.

We invite public comment on our proposed reconsideration procedures.

F. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for rate year (RY) 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during such rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable rate year.

We note that section 1886(s)(4)(A)(i) of the Act uses the term ''rate year.'' Beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD–9–CM codes, which are effective on October 1 of each year. The change allows for annual payment updates and the ICD–9–CM coding update to occur on the same schedule and appear in the same **Federal Register** document, thus making updating rules more administratively efficient. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the 12-month period of October 1 through September 30 is referred to as a fiscal year (76 FR 26435). For more information regarding this terminology change, we refer readers to the ''Changing the IPF PPS Payment Rate Update Period from a Rate Year to a Fiscal Year'' section of the final rule (76 FR 26434 through 26435). For purposes of the discussion below, the term ''rate year'' and ''fiscal year'' both refer to the period beginning October 1 and ending September 30. To avoid confusion that may be caused by using the term ''rate year'' with respect to the inpatient psychiatric hospitals and psychiatric units quality reporting program, we will use the term ''fiscal year'' rather than ''rate year'' throughout this proposed rule, even when we are referring to statutory provisions that refer to ''rate year.''

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 for a fiscal year,

and may result in payment rates under section 1886(s)(1) of the Act being less than such payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We generally prefer to adopt NQF-endorsed measures in our reporting programs with some exceptions as provided by law.

For purposes of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Finally, pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary shall publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the quality reporting program. Such procedures must ensure that a facility has the opportunity to review its data prior to such data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on a CMS Web site.

2. Application of the Payment Update Reduction for Failure to Report for FY 2014 Payment Determination and Subsequent Years

Beginning in FY 2014, section 1886(s)(4)(A)(i) of the Act requires the application of a 2.0 percentage point reduction to the applicable annual update to a Federal standard rate for those psychiatric hospitals and units that fail to comply with the quality reporting requirements implemented in accordance with section 1886(s)(4)(C) of the Act, as detailed below. The application of the reduction may result in an annual update for a fiscal year that is less than 0.0 and in payment rates for a fiscal year being less than the payment rates for the preceding fiscal year. Pursuant to section 1886(s)(4)(B) of the Act, any such reduction is not cumulative and it will apply only to the fiscal year involved. We are proposing to add new regulatory text at 42 CFR 412.424 to codify these requirements.

We invite public comment on the proposed language for the application of the payment reduction to an annual update to a standard Federal rate for failure to report for FY 2014 and subsequent years.

3. Covered Entities

The quality reporting requirements in this proposed rule would cover those psychiatric hospitals and psychiatric units that are reimbursed under Medicare's IPF PPS (42 CFR 412.404(b)). For more information on the application of and exceptions to the IPF PPS reimbursement, we refer readers to the ''Overview of the IPF PPS Payment Methodology'' section of the November 15, 2004 final rule titled ''Medicare Program: Prospective Payment System for Inpatient Psychiatric Facilities'' (69 FR 66922 at 66926). In this proposed rule, we are using the term ''inpatient psychiatric facility'' (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology we have used in the past in our IPF PPS regulations (42 CFR 412.402).

4. Proposed Quality Measures

a. Considerations in Selecting Quality Measures

For purposes of the IPFQR Program, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. The statutory requirements under section 1886(s)(4)(D)(ii) of the Act provide an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In implementing the IPFQR Program, our overarching objective is to support the HHS National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care (*http://www.ahrq.gov/workingforquality/nqs/#aims*). Implementation of the IPFQR Program will help achieve the three-part aim by creating transparency around the quality of care at IPFs to support patient decision-making and quality improvement. Over time, the IPFQR Program will help align the goals for quality measurement and improvement at IPFs with those of other providers in the health system.

We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. We have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We applied the following considerations for the development and selection of measures:

- Given the availability of well-validated measures and the need to balance breadth with minimizing burden, the measures should address as fully as possible the six domains of measurement that arise from the six priorities of the National Quality Strategy: clinical care; person- and caregiver-centered experience and outcomes; safety; efficiency and cost reduction; care coordination; and community/population health.
- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of

care measures, including measures of care transitions and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible.

• The measure sets should evolve so that they include a focused set of measures appropriate to the IPF provider category that reflects the level of care and the most important areas of service and measures for such providers as well as measures addressing a core set of measure concepts that align quality improvement objectives across all provider types and settings.

• Measures should address gaps in quality of inpatient psychiatric care.

• As part of our burden reduction efforts, we continuously seek to weigh the relevance and utility of the measures compared to the burden on hospitals in submitting data under the IPFQR Program. As appropriate, we will align our measures with other Medicare and Medicaid programs and may consider the adoption of meaningful use standards for health information technology (HIT), so that the collection of performance information is part of care delivery.

• To the extent practicable, measures used by CMS should be nationally endorsed by a multistakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature. We consider suggestions and input from technical expert panels (TEPs), convened by CMS contractors, which evaluate IPFQR quality measures for importance, scientific soundness, usability, and feasibility.

We also take into account national priorities and HHS Strategic Plans and Initiatives:

• HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act, which pursues three aims (better care, healthy people, and affordable care) that establish a framework with six identifiable priorities (*http://www.hhs.gov/secretary/about/priorities.html* and *http://www.ahrq.gov/workingforquality/ngs*):

•• Ensuring that each person and family is engaged as partners in their care.

•• Promoting effective communication and coordination of care.

•• Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.

•• Working with communities to promote wide use of best practices to enable healthy living.

•• Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

•• Making care safer by reducing harm caused in the delivery of care.

• We consider recommendations of the Measure Application Partnership (MAP) for the inclusion of clinical quality measures (*http://www.qualityforum.org.map/*). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs.

• HHS is the United States Government's principal department for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. The goals of the HHS Strategic Plan for FYs 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/secretary/about/priorities.html*). HHS will update this strategic plan every 4 years and measure its progress in addressing specific national problems, needs, or mission-related challenges.

HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries, and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-Associated Infections in clinical settings and the Partnership for Patients exemplify these programs.

• CMS Strategic Plan—CMS strives: (1) To ensure measures for different Medicare and Medicaid programs are aligned with priority quality goals, measure specifications are aligned across settings, and outcome measures are used whenever possible; and (2) to move towards the collection of quality measures from electronic health records (EHRs) as appropriate.

We invite public comments on the considerations used for the development and selection of the proposed quality measures for the IPFQR Program.

b. Proposed Quality Measures Beginning With FY 2014 Payment Determination and Subsequent Years

We are proposing to adopt six quality measures for FY 2014 and subsequent fiscal years. In selecting the proposed quality measures discussed below, we strive to achieve several objectives. First, we believe the measures we are proposing relate to the general aims of better care, better health, and lower cost and address the six domains of quality measurement as fully as possible. Second, we believe the measures are tailored to the needs of improved quality in IPFs; thus, the measures selected are those most relevant to IPFs. Third, we believe the measures promote alignment of quality improvement objectives across provider settings. Finally, we believe the measures are minimally burdensome to IPFs.

We recognize that any quality reporting program will impose certain data collection and reporting requirements on participating facilities. However, we believe that the proposed measures minimize the collection and reporting burden on IPFs because, under Medicare's IPF conditions of participation (CoPs) (42 CFR 482.61), IPFs must maintain documentary evidence of detailed treatment approaches and aftercare considerations. Further, under 42 CFR 482.21, IPFs are required to develop, implement, and maintain an effective, ongoing, hospital-wide data-driven quality assessment and performance improvement (QAPI) program as well as documentary evidence of such program for purposes of demonstrating their operation to CMS. More importantly, § 482.21 requires that IPFs measure, analyze, and track certain quality indicators, including adverse patient events, and other aspects of performance that enable the hospital to assess processes of care, hospital services, and operations as part of their QAPI Program. Because the proposed IPFQR Program measures cover processes that IPFs are currently recording as Medicare CoPs, we do not believe that reporting on the proposed measures would impose a significant burden on IPFs. We note that over one-quarter of IPFs [198] are also already reporting data needed to calculate the proposed measures to The Joint Commission (TJC) for purposes of TJC accreditation. Thus, the IPFQR Program

[198] Out of the 1,741 existing IPFs, 450 are currently reporting the proposed measures to TJC. This equates to approximately 26 percent of IPFs that already report the measures on a regular basis.

will impose little additional burden for those IPFs.

After considering the recommendations and feedback from content area experts and multiple stakeholders, we are proposing, for the FY 2014 payment determination and subsequent years, six NQF-endorsed, Hospital-Based Inpatient Psychiatric Services (HBIPS) measures, which have been developed by and are maintained by TJC for purposes of assessing the quality of inpatient psychiatric services. These measures are: (1) HBIPS–2: Hours of Physical Restraint Use (NQF #0640); (2) HBIPS–3: Hours of Seclusion Use (NQF #0641); (3) HBIPS–4: Patients Discharged on Multiple Antipsychotic Medications (NQF #0552); (4) HBIPS–5: Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (NQF #0560); (5) HBIPS–6: Post-Discharge Continuing Care Plan Created (NQF #0557); and (6) HBIPS–7: Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge (NQF #0558).[199] These six proposed process measures are NQF-endorsed and were recommended by the MAP[200] for inclusion in the IPFQR Program. The six proposed measures align with three of the six priorities of the National Quality Strategy: patient safety, promoting effective prevention and treatment practices (clinical quality of care), and promoting effective communication and coordination of care. Technical specifications for these measures can currently be found on the Web site of TJC, the measure steward, at: *http://www.manual.jointcommission.org/releases/TJC2012B/HospitalBasedInpatientPsychiatricServices.html*.

As noted earlier, these six HBIPS measures are currently in use by an estimated 450 TJC-accredited IPFs, thereby posing minimal collection burden for these facilities. We note that an estimated 1,100 facilities, which do not routinely report to TJC, will incur some data collection burden. In addition, summary analyses of current measure results provided to CMS by TJC demonstrate variation in performance among the facilities currently reporting results for these measures, suggesting continued opportunity for quality improvement.

Section 1886(s)(4)(D)(i) of the Act requires that quality measures selected for the IPFQR Program be endorsed by the entity with a contract under section 1890(a) of the Act. As discussed earlier, the current holder of this contract is NQF. The measures are currently NQF-endorsed for reporting overall performance rates and rates for four age groups (children, adolescents, adults, and older adults). We are proposing to require reporting of data for all four age groups for which the measures are currently endorsed. More details regarding this proposal are included in section VIII.F.7. of this preamble. In addition to aligning with previous collection and reporting of these measures by TJC, our proposal reflects the feedback provided by the subject-matter TEP convened by the CMS measure development contractor for this program and focus groups of hospitals and vendors involved in providing inpatient psychiatric services.

We are proposing to collect aggregate data rather than patient level data for FY 2014 and subsequent years in recognition of the considerable burden to providers not accustomed to reporting patient level data. Hospitals are free to use our paper abstraction tool and utilize commonly available software, like spreadsheets, to enter and compute measure rates. We intend to provide a template using a commonly available spreadsheet format used by many hospitals which will be available on the QualityNet Web site (*http://www.qualitynet.org/*). Further, IPFs are free to procure services from TJC vendors to assist them with data collection. However, we note that we do not require the use of TJC vendors. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble. The six proposed measures for FY 2014 and subsequent years are described in more detail below.

(1) HBIPS–2 (Hours of Physical Restraint Use)

The use of physical restraints increases a patient's risk of physical injury as well as psychological harm.[201,202] This intervention is intended for use only if a patient is in imminent danger to him/herself or others and if less restrictive interventions have failed. It is not intended to address staff shortages or to be used as a form of discipline or coercion. The President's New Freedom Commission on Mental Health[203] explicitly recommends the reduction of restraint use to improve quality of care. A measure designed to reduce the use of restraints will also help achieve the National Quality Strategy's goal to improve patient safety and reduce the risk of harm from care.

In addition to initiatives to reduce the use of restraints, the subject-matter TEP convened by our measure development contractor identified patient safety as an important measure concept and recommended the use of HBIPS–2 (Hours of Physical Restraint Use) for use in a national IPF quality reporting program. HBIPS–2 is a process measure that is reported as the total number of hours of physical restraint (HBIPS–2) use for all patients admitted to an inpatient psychiatric facility. We believe that fewer reported hours of physical restraint use suggest higher quality of care because reduced restraint time lowers patient risk for physical injury and psychological harm.

The numerator is defined as the total number of hours that all psychiatric inpatients were maintained in physical restraint. The denominator is defined as the number of psychiatric inpatient hours overall. Total leave days are excluded from the denominator.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–2 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting the measure for purposes of TJC accreditation. HBIPS–2 received support from the MAP and is aligned with the National Quality Strategy priority for providing safer care.

We invite public comments on the inclusion of the proposed quality measure HBIPS–2, Hours of Physical Restraint Use, in the IPFQR program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(2) HBIPS–3 (Hours of Seclusion Use)

The use of seclusion increases a patient's risk of physical injury as well

[199] The Joint Commission has developed seven Hospital-Based Inpatient Psychiatric Services (HBIPS) measures. Only six of these seven measures are proposed for the FY 2014 payment determination; HBIPS–1 is not proposed.

[200] Measure Application Partnership, *Pre-Rulemaking Final Report: Input on Measures under Consideration by HHS for 2012 Rulemaking,* pages 95–96, Available at: *http://www.qualityforum.org/map/*.

[201] Evans, D., Wood, J., & Lambert, L. (2003). Patient injury and physical restraint devices: A systematic review. Journal of Advanced Nursing, 41: 274–282.

[202] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

[203] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

as psychological harm.[204,205] This intervention is intended for use only if a patient is in imminent danger to him/herself or others and if less restrictive interventions have failed. It is not intended to address staff shortages or to be used as a form of discipline or coercion. The President's New Freedom Commission on Mental Health explicitly recommends the reduction of seclusion use to improve quality of care.[206] Measures designed to reduce the use of seclusion will also help achieve the National Quality Strategy's goal to improve patient safety and reduce the risk of harm from care.

The subject-matter TEP convened by our measure development contractor identified patient safety as an important measure concept and recommended the use of HBIPS–3 (Hours of Seclusion Use) for use in a national IPF quality reporting program. HBIPS–3 is a process measure that is reported as the total number of hours of seclusion use for all patients admitted to an IPF. We believe that fewer reported hours of seclusion use suggest higher quality of care because reducing seclusion time lowers patient risk for physical injury and psychological harm.

The numerator is defined as the total number of hours all psychiatric inpatients were held in seclusion. The denominator is defined as the number of psychiatric inpatient hours overall. Total leave days are excluded from the denominator.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–3 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting the measure for purposes of TJC accreditation. HBIPS–3 received support from the MAP and is aligned with the National Quality Strategy priority for providing safer care.

We invite public comment on the inclusion of the proposed quality measure HBIPS–3, Hours of Seclusion Use, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(3) HBIPS–4 (Patients Discharged on Multiple Antipsychotic Medications)

An estimated 30 percent to 50 percent of patients in IPFs are treated with two or more antipsychotic medications, which can lead to serious side effects. Among patients without a history of treatment failure on a single antipsychotic, there is insufficient evidence to conclude that patients experience better outcomes if they are prescribed multiple antipsychotics compared to a single antipsychotic. Given the risk of side effects, stakeholders such as the National Association of State Mental Health Program Directors have called for the reduction of unnecessary use of multiple antipsychotics.[207] The American Psychiatric Association recommends the use of multiple antipsychotics only if a patient has had failed attempts on single antipsychotics. In efforts to promote effective treatment practices, a National Quality Strategy priority, we are proposing to include the process measure HBIPS–4, Patients Discharged on Multiple Antipsychotic Medications, in the FY 2014 IPFQR Program. The MAP and the subject-matter TEP convened by our measure development contractor support the inclusion of this measure in the IPFQR Program.

TJC designed HBIPS–4 as part of a paired set with HBIPS–5 (described below), meaning they were developed to be used together. HBIPS–4 is collected on all patients admitted to an IPF and is reported as the rate of patients discharged on multiple antipsychotics. We believe that lower rates are indicative of higher quality of care because reducing the use of multiple antipsychotics reduces the potential risks of harmful side effects to patients. However, there is no expectation that zero percent is the desired outcome because it is recognized that in some circumstances, use of multiple antipsychotics may be appropriate.

The numerator is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications. The denominator is defined as all psychiatric inpatient discharges. The measure excludes patients who died, patients with an unplanned departure resulting in discharge due to elopement, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

Taken together, HBIPS–4 and HBIPS–5 are intended to help reduce unnecessary use of multiple antipsychotics and to promote better clinical outcomes and reduced side effects for patients.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–4 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs already are collecting and reporting the measure for purposes of TJC accreditation. HBIPS–4 received support from the MAP and is aligned with the National Quality Strategy priority for promoting effective prevention and treatment practices.

We invite public comment on the inclusion of the proposed quality measure HBIPS–4, Patients Discharged on Multiple Antipsychotic Medications, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(4) HBIPS–5 (Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification)

In efforts to promote effective treatment practices, a National Quality Strategy priority, we are proposing to include the process measure HBIPS–5, Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification, in the FY 2014 IPFQR Program. The MAP and the subject-matter TEP convened by our measure development contractor support the inclusion of this measure in the IPFQR Program.

TJC designed HBIPS–5 as part of a paired set with HBIPS–4, meaning they were developed to be used together. HBIPS–5 is collected on those patients discharged on multiple antipsychotics and is reported as the rate of patients discharged on multiple antipsychotics with appropriate justification. This measure was designed in recognition that there is a subsample of patients for whom multiple antipsychotic use may be appropriate. TJC has identified the following justifications as appropriate reasons for discharging a patient on

[204] Holmes, D., Kennedy, S.L., & Perron, A. (2004). The mentally ill and social exclusion: a critical examination of the use of seclusion from the patient's perspective. Issues in Mental Health Nursing, 25: 559–578.

[205] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

[206] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

[207] National Association of State Mental Health Program Directors. Technical report on polypharmacy. Alexandria, VA: 2001. Retrieved from *http://www.nasmhpd.org/general_files/publications/med_directors_pubs/Polypharmacy.PDF.*

multiple antipsychotics: (1) The medical record contains documentation of a history of a minimum of three failed trials of monotherapy; (2) the medical record contains documentation of a recommended plan to taper to monotherapy or documentation of a plan to decrease the dosage of one or more antipsychotic medications while increasing the dosage of another antipsychotic medication to a level that manages the patient's symptoms with one antipsychotic medication (that is, cross-taper); and (3) the medical record contains documentation of augmentation of Clozapine. Higher rates on HBIPS–5 indicate higher quality of care because documenting the reasons for assigning two or more antipsychotics suggests that careful consideration of the benefits of this course of treatment were weighed against the potential patient side effects.

The numerator statement is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications with appropriate justification. The denominator is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications. The measure excludes patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients with an unplanned departure resulting in discharge due to failing to return from leave, and patients with a length of stay less than or equal to 3 days.

Taken together, we believe that HBIPS–4 and HBIPS–5 will help reduce unnecessary use of multiple antipsychotics and will lead to better clinical outcomes and reduced side effects for patients.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–5 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS–5 received support from the MAP and is aligned with the National Quality Strategy priority for promoting effective prevention and treatment practices.

We invite public comment on the inclusion of the proposed quality measure HBIPS–5, Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(5) HBIPS–6 (Post-Discharge Continuing Care Plan Created)

When patients are discharged from the hospital, they may benefit from communication of information regarding the care they received or recommendations for their continued care. For a seamless transition from one treatment setting to another, providers that receive patients from inpatient settings need to know information regarding the patient's treatment during hospitalization, recommendations for post-discharge care, and any medications the patient was discharged on. A discharge plan facilitates this transition of information from one setting to another and has been shown to have positive effects on readmissions.

The promotion of effective care coordination is a National Quality Strategy priority. We are proposing process measure HBIPS–6, Post-Discharge Continuing Care Plan Created, to promote care coordination for patients in inpatient psychiatric settings. TJC designed HBIPS–6 as part of a paired set with HBIPS–7; they were developed to be used together. HBIPS–6 measures whether a post-discharge continuing care plan is created. However, the creation of a care plan does not necessarily mean the plan is communicated to the patient's next provider. Therefore, HBIPS–7 measures whether a post-discharge continuing care plan is created and transmitted to the next level of care provider. Together, these two measures can assist facilities in determining where breakdowns in care processes occur. Quality care under HBIPS–6 is indicated by patients who are discharged with a continuing care plan that includes the reason for the hospitalization, the principal discharge diagnosis, discharge medications, and the next level of care recommendations. HBIPS–6 is collected on all patients admitted to IPFs. We believe that higher rates on this measure suggest better quality of care because greater numbers of post-discharge plans indicate greater opportunities for improved patient-provider and provider-provider communication, thus leading to improved patient care and health.

The numerator is defined as psychiatric inpatients for whom the post-discharge continuing care plan is created and contains all of the following: Reason for hospitalization, principal discharge diagnosis, discharge medications, and next level of care recommendations. The denominator is defined as all psychiatric inpatient discharges. Populations excluded from the denominator include patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients or their guardians who refused aftercare, patients or guardians who refused to sign authorization to release information, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–6 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. It is appropriate to facility-level assessment of quality of care provided by IPFs. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS–6 received support from the MAP and is aligned with the National Quality Strategy priority for promoting better care coordination.

We invite public comment on the inclusion of the proposed quality measure HBIPS–6, Post-Discharge Continuing Care Plan Created, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(6) HBIPS–7 (Post-Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider Upon Discharge)

The promotion of effective care coordination is a National Quality Strategy priority. We are proposing process measure HBIPS–7, Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider upon Discharge, to promote care coordination for patients in inpatient psychiatric settings. TJC designed HBIPS–7 as part of a paired set with HBIPS–6; they were developed to be used together. While the creation of a discharge care plan (as measured in HBIPS–6) is an important part of providing coordinated care, simply creating the plan does not ensure that the necessary information is transferred to the patient's next provider. HBIPS–7 measures both aspects of coordinated care—the creation of a discharge plan and the transmittal of that plan to the next provider. Together, these two measures can assist facilities in determining where breakdowns in care processes occur. As specified by TJC, the discharge plan should be transmitted by the fifth post-discharge day. This measure is collected on all patients admitted to IPFs. We believe

that higher rates on this measure suggest better quality care because the greater the number of post-discharge plans created and transmitted, the greater opportunities for improved patient-provider and provider-provider communication and understanding of what is necessary to improve patient health.

The numerator is defined as psychiatric inpatients for whom the post-discharge continuing care plan was transmitted to the next level of care. The denominator statement is defined as all psychiatric inpatient discharges. Populations excluded from the denominator include patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients who refused (or whose guardians refused) aftercare, patients who refused to sign (or whose guardians refused to sign) authorization to release information, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–7 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS–7 received support from the MAP and is aligned with the National Quality Strategy priority for promoting better care coordination.

We invite public comment on the inclusion of the proposed quality measure HBIPS–7, Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider upon Discharge, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

In summary, we are proposing to include six quality measures to be reported in aggregate form for FY 2014 and subsequent years. These six measures are shown in the table below. Measures adopted for the IPFQR Program would remain in the quality program for all subsequent years unless specifically stated otherwise (for example, through removal or replacement). Proposals for collection requirements and submission timeframes for these measures are included in section VIII.F.7. of this preamble.

PROPOSED QUALITY MEASURES BEGINNING WITH THE FY 2014 IPFQR PROGRAM

National quality strategy priority	NQF No.	Measure ID	Measure description
Patient Safety	0640	HBIPS–2	Hours of Physical Restraint Use.
	0641	HBIPS–3	Hours of Seclusion Use.
Clinical Quality of Care	0552	HBIPS–4	Patients Discharged on Multiple Antipsychotic Medications.
	0560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
Care Coordination	0557	HBIPS–6	Post-Discharge Continuing Care Plan Created.
	0558	HBIPS–7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge.

c. Maintenance of Technical Specifications for Quality Measures

We will provide a user manual that will contain links to measure specifications, data abstraction information, data submission information, a data submission mechanism known as the Web-based Measure Tool, and other information necessary for IPFs to participate in the IPFQR Program. This manual will be posted on the QualityNet Web site at: *https://www.QualityNet.org*. We will maintain the technical specifications for the quality measures by updating this manual periodically and including detailed instructions for hospitals to use when collecting and submitting data on the required measures. These updates will be accompanied by notifications to IPFQR Program participants, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for NQF-endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the IPFQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We also would post the updates on the CMS QualityNet Web site at *https://www.QualityNet.org*. We would provide sufficient lead time for IPFs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal

adequately balances our need to incorporate NQF updates to NQF-endorsed IPFQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

5. Possible New Quality Measures for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the inpatient psychiatric setting. Therefore, through future rulemaking, we intend to propose new measures that will help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services, through the widespread dissemination and use of performance information. Additionally, we are considering initiating a call for future measures to solicit input to assess the following measure domains: Clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. This approach will enhance better psychiatric care while bringing the IPFQR Program in line with other established quality reporting and performance improvement programs such as the Hospital IQR Program, the Hospital OQR Program, the ESRD QIP, and other CMS quality programs.

We welcome public comment on considerations of additional measure topics for the IPFQR Program in future rulemaking.

6. Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making the data submitted under the IPFQR Program available to the public. Such procedures shall ensure that an IPF has the opportunity to review the data that is to be made public with respect to the psychiatric hospital or unit prior to such data being made public. The data collected will be displayed on our Web site. Under these requirements, for each payment determination year, we are proposing to publicly display the submitted data on our Web site beginning in the first quarter of the calendar year following the respective payment determination year. Before the data are publicly displayed, we are proposing that IPFs will have the opportunity to preview their data between September 20 and October 19 of the respective payment determination year (refer to the following table).

PROPOSED PUBLIC DISPLAY FOR FY 2014, FY 2015, AND FY 2016

Payment determination year (fiscal year)	30-day preview period	Public display (calendar year)
FY 2014	September 20, 2013–October 19, 2013	2014
FY 2015	September 20, 2014–October 19, 2014	2015
FY 2016	September 20, 2015–October 19, 2015	2016

We believe this timeframe allows for sufficient time for both IPFs and CMS to correct any potential mistakes and fulfill the preview requirement in section 1886(s)(4)(E) of the Act.

We welcome public comment on the proposed preview and public display procedures for FY 2014 and subsequent years.

7. Form, Manner, and Timing of Quality Data Submission for the FY 2014 Payment Determination and Subsequent Years

a. Background

Section 1886(s)(4)(C) of the Act requires that, for the FY 2014 payment determination and each subsequent year, each IPF submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(s)(4)(A) of the Act, for any IPF that fails to submit quality data in accordance with section 1886(s)(4)(C) of the Act, the Secretary will reduce any annual update to a standard Federal rate for discharges occurring during such fiscal year by 2.0 percentage points. The complete data submission requirements, submission deadlines, and data submission mechanism known as the Web-Based Measure Tool will be posted on the QualityNet Web site at: *http://www.qualitynet.org/*. The Web-Based Measure Tool is an Internet database for IPFs to submit their aggregate data. We are proposing that IPFs submit data in accordance with the specifications for the appropriate proposed reporting periods to the Web-Based Measures Tool found in the IPF section on the QualityNet Web site (*http://www.qualitynet.org/*). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act (HIPAA) requirements for security of protected health information.

b. Proposed Procedural Requirements for the FY 2014 Payment Determination and Subsequent Years

In order to participate in the IPFQR Program for the FY 2014 payment determination and subsequent years, we are proposing that IPFs must comply with the procedural requirements outlined below. We have aligned these procedural requirements with the Hospital IQR Program to avoid imposing additional burden on providers and to increase efficiencies by virtue of allowing providers to use similar submission requirements across programs. We are proposing that facilities must do the following:

- Register with QualityNet before the IPF begins reporting, regardless of the method used for submitting the data.
- Identify a QualityNet Administrator who follows the registration process located on the QualityNet Web site (*http://www.qualitynet.org/*).
- Complete a Notice of Participation (NOP). IPFs that wish to participate in the IPFQR Program must complete an online NOP. Submission of an NOP is an indication that the IPF agrees to participate in the IPFQR Program and public reporting of their measure rates. The timeframe for completing the NOP is between January 1 and August 15 before each respective payment determination year. Accordingly, for the FY 2014 payment determination year, we are proposing that the timeframe for completing the NOP would be between January 1, 2013 and August 15, 2013.
- Any IPF that receives a new CMS Certification Number (CCN) on or after the beginning of the respective payment

determination year and wishes to participate in the IPFQR Program but has not otherwise submitted a NOP using the new CCN must submit a completed NOP no later than 180 days from the date identified as the open date (that is, the Medicare acceptance date) on the approved CMS Quality Improvement Evaluation System to participate in the IPFQR Program.

- Withdrawals from the IPFQR Program will be accepted no later than August 15 before the beginning of each respective payment determination year. We believe the August 15 deadline will give us sufficient time to update payment determinations for each respective year. Accordingly, we are proposing that the withdrawal period for the FY 2014 payment determination year be between January 1, 2013 and August 15, 2013. If in a given payment determination year, an IPF withdraws from the program, it will receive a reduction of 2.0 percentage points to that year's applicable percentage increase. Once an IPF has submitted a NOP, it is considered to be an active IPFQR participant until such time as the IPF submits a withdrawal form to CMS.
- We will determine if an IPF has complied with our data submission requirements by validating each IPF's CCN and their aggregated data submission on the QualityNet Web site.
- IPFs must submit the aggregated numerator and denominator data for all age groups, for all measures, to avoid the 2.0 percentage point reduction.

As previously noted, we believe that this proposed aggregated data collection mode using a Web page will reduce burden to IPFs. We anticipate that IPFs already reporting de-identified patient level data to TJC would be able to easily aggregate and report these data on a secure Web page to CMS.

We welcome public comment on the proposed procedural requirements for the FY 2014 payment determination and subsequent years.

c. Proposed Reporting and Submission Requirements for the FY 2014 Payment Determination

IPFs choosing to participate in the IPFQR Program must meet the specific data collection and submission requirements as described on the QualityNet Web site (*http://www.qualitynet.org/*) and TJC's Specifications Manual for Joint Commission National Quality Measures (Specifications Manual) at: *http://www.manual.jointcommission.org/releases/TJC2012B/HospitalBasedInpatientPsychiatricServices.html*. We note that the Specifications Manual is updated at least twice a year (and may be updated more often as necessary), and IPFs are responsible for using the requirements in the most recent manual. The most current version can be found on the Web site at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*. We are proposing that IPFs submit aggregate data on the measures on an annual basis, beginning FY 2014. As noted earlier, IPFs must submit the data to the Web-Based Measures Tool found in the Inpatient Psychiatric Facility section on the QualityNet Web site. However, the data input forms on the QualityNet Web site for such submission will require aggregate data for each separate quarter. Therefore, IPFs will need to track and maintain quarterly records for their data.

For the FY 2014 payment determination, we are proposing that IPFs report on the proposed measures for services provided between Q4 of CY 2012 and Q1 of CY 2013. These two quarters' data constitute the expected data available to CMS when we assess reporting compliance. The 6-month timeframe will allow us to establish a full calendar year of reporting by FY 2016 as discussed below. We are proposing that IPFs submit their aggregated data between July 1, 2013 and August 15, 2013. The following table summarizes this information.

PROPOSED QUALITY REPORTING AND SUBMISSION TIMEFRAMES FOR FY 2014

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data submission timeframe
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012). Q1 2013 (January 1, 2013–March 31, 2013)	July 1, 2013–August 15, 2013.

We welcome public comment on the proposed reporting and data submission requirements for the FY 2014 payment determination.

d. Proposed Reporting and Submission Requirements for the FY 2015 and FY 2016 Payment Determinations

We are proposing that IPFs report on measures for services provided in Q2, Q3, and Q4 of CY 2013 for the FY 2015 payment determination and in Q1, Q2, Q3, and Q4 of CY 2014 for the FY 2016 payment determination. For FY 2014 and FY 2015, we are proposing that IPFs report data on the proposed measures for inpatient psychiatric services provided for 6 and 9 months, respectively, to move towards data reporting of services provided within a full calendar year (12 months) by FY 2016. We have summarized this proposal in the following table.

PROPOSED QUALITY REPORTING AND SUBMISSION TIMEFRAMES FOR FY 2015 AND FY 2016 PAYMENT DETERMINATIONS

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data submission timeframe
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013). Q4 2013 (October 1, 2013–December 31, 2013).	July 1, 2014–August 15, 2014.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014). Q3 2014 (July 1, 2014–September 30, 2014). Q4 2014 (October 1, 2014–December 31, 2014).	July 1, 2015–August 15, 2015.

The reporting of data within the timeframes outlined previously will allow us to align the IPFQR Program with other quality reporting programs that base their data reporting on a calendar year.

We welcome public comment on the proposed reporting and data submission requirements for the FY 2015 and FY 2016 payment determinations.

e. Proposed Population, Sampling, and Minimum Case Threshold for FY 2014 and Subsequent Years

We are proposing that participating IPFs must meet specific population, sample size, and minimum reporting case threshold requirements as specified in TJC's Specifications Manual. The Specifications Manual is updated at least twice a year (and may be updated more often as necessary), and IPFs must follow the requirements in the most recent manual. The most current version can be found on the Web site at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*.

We are proposing that the target population for the proposed measures include all patients, not solely Medicare beneficiaries. We believe it is important to require IPFs to submit measures on all patients because quality improvement is of industry-wide importance and should not be focused exclusively on a certain subset of patients. We are proposing that IPFs use the applicable sample size requirements found in the Specifications Manual. We note that the Specifications Manual gives providers the option of sampling their data quarterly or monthly. We note that the Specifications Manual does not require sampling procedures for measures HBIPS–2 and HBIPS–3. Therefore, IPFs are required to submit data on all cases for these two measures.

The Specifications Manual uses the term ''minimum required stratum sample size'' to refer to the required sample size for a given initial patient population stratum.[208] To comply with our proposed reporting requirements, if the initial patient population stratum size is below a certain number of cases,[209] for measures HBIPS–4, HBIPS–5, HBIPS–6, and HBIPS–7, IPFs must submit all applicable measure data rather than sample data. More details on sampling procedures are located in the Specifications Manual available at the Web site: *https://manual.jointcommission.org/bin/view/Manual/WebHome*.

IPFs that have no data to report for a given measure must enter zero for the population and sample counts. For example, an IPF that has no hours of physical restraint use (HBIPS–2) to report for a given quarter is still required to submit a zero for its quarterly aggregate population and sample count for HBIPS–2 in order to meet the reporting requirement. We believe it is important for IPFs to submit data on all measures even when the population size for a given measure is zero or small because it provides us with the opportunity to identify, assess, and evaluate the baseline for the number of cases for each measure in future years. This will also assist us in determining the minimum case threshold for future years in the rule. In cases where the measure rates are calculated based on low caseloads, when the submitted data are publicly displayed on the QualityNet Web site, we are proposing to clearly note that the affected measure rates were calculated based on low caseloads that may affect the result.

We invite public comment on the proposed population, sampling, and case thresholds and welcome any comments on methods and approaches for future years.

f. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2014 Payment Determination and Subsequent Years

We are proposing to require IPFs to acknowledge their data accuracy and completeness once annually using a QualityNet Web site Web page. To affirm that the data provided to meet the FY 2014 IPFQR Program data submission requirement is accurate and complete to the best of a facility's knowledge, an IPF would be required to submit the Data Accuracy and Completeness Acknowledgment (DACA) form. We would provide a link to this form once IPFs have completed entry of all aggregated measure data. Data submission would not be complete until the IPF submits the DACA form. We are proposing that the deadline for submission of both measure data and the DACA form would be no later than August 15 prior to the applicable IPFQR Program payment determination year.

For the FY 2014 payment determination, for which participating IPFs are required to report data for discharges occurring between Q4 of CY 2012 and Q1 of CY 2013, we are proposing to make the submission deadline for the DACA no later than August 15, 2013. We are proposing that the DACA submission deadlines for FY 2015 and FY 2016 would be August 15 of CY 2014 and CY 2015, respectively. We are proposing August 15 as the DACA submission deadline for several reasons. First, requiring IPFs to acknowledge their data's accuracy and completeness by August 15 of the year before the respective payment determination year provides us with sufficient time to ensure compliance with the program by October 1, the start of the fiscal year, and, therefore, with sufficient time to calculate and apply the annual payment update. Second, we believe that it is reasonable to make the deadline for DACA the same as the data submission deadline in order to reduce reporting burden to hospitals. Lastly, using August 15 as the DACA deadline allows us to align our data acknowledgment deadline with other quality reporting programs, such as the Hospital IQR Program. The table below summarizes this information.

PROPOSED DATA ACCURACY AND COMPLETENESS ACKNOWLEDGMENT (DACA) DEADLINES FOR FY 2014, FY 2015, AND FY 2016 PAYMENT DETERMINATIONS

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data accuracy and completeness acknowledgement deadline
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012) Q1 2013 (January 1, 2013–March 31, 2013).	August 15, 2013.
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013). Q4 2013 (October 1, 2013–December 31, 2013).	August 15, 2014.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014)	August 15, 2015.

[208] For example, for initial population stratum size of 211–877, the most current version of the Specifications Manual requires a minimum stratum sample size of 20 percent of the initial population stratum size. If the initial population size is 44–220, the minimum required stratum sample size is 44.

[209] In the most current version of the Specifications Manual this number is 44.

PROPOSED DATA ACCURACY AND COMPLETENESS ACKNOWLEDGMENT (DACA) DEADLINES FOR FY 2014, FY 2015, AND FY 2016 PAYMENT DETERMINATIONS—Continued

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data accuracy and completeness acknowledgement deadline
	Q2 2014 (April 1, 2014–June 30, 2014). Q3 2014 (July 1, 2014–September 30, 2014). Q4 2014 (October 1, 2014–December 31, 2014).	

We invite public comment on our proposed DACA requirements.

8. Reconsideration and Appeals Procedures for the FY 2014 Payment Determination and Subsequent Years

In the event an IPF believes that its annual payment update has been incorrectly reduced for failure to report under the IPFQR Program, we are proposing a reconsideration process whereby IPFs can request a reconsideration of their payment update reduction. We are proposing to institute an annual reconsideration process similar to the Hospital IQR program (74 FR 43892). We would not utilize reconsideration policies and procedures related to the Hospital IQR Validation requirement because the IPFQR does not currently propose an annual validation requirement for IPFs. For FY 2014 and subsequent years, we are proposing that the deadline for IPFs to submit a request for reconsideration of their payment determination would be 30 days from the date identified on the payment determination notification letter. While we want to ensure that IPFs have an opportunity to request reconsiderations when warranted, we also need to balance this goal with our need to complete the reconsideration process in a timely manner and with the IPFs' need to obtain final decisions on their requests in a timely manner. We believe that a 30-day timeframe best achieves this balance.

We believe that requiring providers to submit a request for reconsideration prior to filing an appeal before the Provider Reimbursement Review Board (PRRB) is more efficient for both CMS and IPFs because it decreases the number of appeals by resolving issues earlier in the process. We are proposing that, together with a request for reconsideration, an IPF must submit all documentation and evidence that supports its request for reconsideration. The documentation should include copies of any communication, such as emails, that the IPF believes demonstrates its compliance with the program requirements, as well as any other records that may support the IPF's rationale for seeking reconsideration.

We are proposing to codify the reconsideration procedures that IPFs must follow at new § 412.434 under 42 CFR Part 412, Subpart N. Under these procedures, an IPF must submit to CMS, no later than 30 days from the date identified on the IPFQR Program payment determination notification letter provided to the IPF, a Reconsideration Request form containing the following information:

- The IPF's CMS Certification Number (CCN).
- The name of the IPF.
- Contact information for the IPF's chief executive officer and QualityNet system administrator, including each individual's name, email address, telephone number, and physical mailing address.
- A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the IPF did not meet the requirements of the IPFQR Program.
- A detailed explanation of why the IPF believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year.
- Any evidence that supports the IPF's reconsideration request, such as e-mails and other documents.

Following receipt of a request for reconsideration, we will provide—

- An email acknowledgment, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator that the request has been received; and
- Written notification to the hospital CEO, using the contact information provided in the reconsideration request, regarding our decision. We expect the process to take approximately 90 days from the receipt of the reconsideration request.

We are proposing that IPFs must submit a request for reconsideration, as described previously, and receive a decision on that request from CMS before they can file an appeal with the PRRB. If dissatisfied with the decision rendered at the reconsideration level, IPFs can appeal the decision with the PRRB under 42 CFR Part 405, Subpart R. We are proposing to codify this requirement at new § 412.434(c).

We intend to work with our Medicare administrative contractors to process updated IPF claims in an expeditious manner to pay IPFs when our annual payment update reduction decision is overturned in reconsideration or PRRB review. The timeframe for updating payment through retroactive claims processing widely varies, and is dependent on the number of IPFs, the number of affected claims, and the advance time needed by the Medicare administrative contractor.

We invite public comment on the proposed procedures for reconsideration and appeals.

9. Proposed Waivers From Quality Reporting Requirements for the FY 2014 Payment Determination and Subsequent Years

In our experience with other quality reporting and/or performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). It is our goal to avoid penalizing IPFs in such circumstances or to unduly increase their burden during these times. Therefore, we are proposing that, for FY 2014 and subsequent years, IPFs may request and we may grant waivers with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the facility may warrant. When waivers are granted, IPFs will not incur payment reductions for failure to comply with the requirements of the IPFQR Program.

Under the proposed process, in the event of extraordinary circumstances not within the control of the IPF, such as a natural disaster, the IPF may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters. Such facilities would submit a request form to CMS that would be made available on the QualityNet Web site. The following information should be noted on the form:

- The IPF's CCN;
- The IPF's name;

• Contact information for the IPF's CEO and any other designated personnel, including name, email address, telephone number, and mailing address (the address must be a physical address, not a post office box);
• The IPF's reason for requesting an extension or waiver;
• Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
• A date when the IPF will again be able to submit IPFQR Program data, and a justification for the proposed date.

We are proposing that the request form must be signed by the IPF's CEO, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the request form, we would: (1) Provide a written acknowledgement, using the contact information provided in the request, to the CEO and any additional designated IPF personnel, notifying them that the IPF's request has been received; and (2) provide a formal response to the CEO and any additional designated IPF personnel, using the contact information provided in the request, notifying them of our decision.

This proposal does not preclude us from granting waivers or extensions to IPFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, a hurricane or other natural disaster that could reasonably affect a facility's ability to compile or report data), affects an entire region or locale. If we make the determination to grant a waiver or extension to IPFs in a region or locale, we are proposing to communicate this decision through routine communication channels to IPFs and vendors, by means of memoranda, emails, and notices on the QualityNet Web site, among other means.

We invite public comment on this proposal.

10. Electronic Health Records (EHRs)

Although for initial reporting, the opportunity to utilize EHRs for automatic data collection is not applicable because the proposed measures will be submitted as aggregate data, we encourage IPFs to take steps towards adoption of EHRs (also referred to as electronic medical records) that will allow for reporting of clinical quality data from EHRs directly to a CMS repository. We encourage IPFs that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. Although the IPFQR Program is in its initial implementation stages, we suggest that IPFs take due care and be diligent to ensure that their EHR systems accurately capture quality data and that, ideally, such systems provide point-of-care decision support that promotes optimal levels of clinical performance.

In the future, we will continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting.

We welcome public comment on the adoption of EHRs for the IPFQR Program in the future.

IX. MedPAC Recommendations and Other Related Studies and Reports for the IPPS and the LTCH PPS

A. MedPAC Recommendations for the IPPS for FY 2013

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2012 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2013 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov*.

B. Studies and Reports on Reforming the Hospital Wage Index

1. Secretary's Report to Congress on Wage Index Reform

Section 3137(b) of the Affordable Care Act requires the Secretary of Health and Human Services to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act relating to the IPPS. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by MedPAC in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare.'' This report is available on via the Internet at: *http://www.medpac.gov/documents/jun07_entirereport.pdf*, and was discussed in the FY 2009 IPPS final rule (73 FR 48567 through 48574), the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43824 and 43825), and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50158 and 50159.

In developing the Report to Congress required by section 3137(b) of the Affordable Care Act, CMS contracted with Acumen L.L.C. (Acumen) to review the June 2007 MedPAC report and recommend a methodology for an improved Medicare wage index system. (The Acumen reports are available via the Internet on the Web site at: *http://www.acumenllc.com/reports/cms*. After consultation with relevant parties during the development of the plan (which included an April 12, 2011 special wage index reform open door forum, along with a review of electronically submitted comments and concerns), the Secretary submitted a ''Report to Congress—Plan to Reform the Medicare Hospital Wage Index'') that describes the concept of a Commuting Based Wage Index (CBWI) as a potential replacement to the current Medicare wage index methodology. The following is a summary of the highlights of the report. The complete report can be accessed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*.

As discussed in section III.B. of the preamble of this proposed rule, the current wage index methodology relies on labor markets that are based on statistical area definitions (Core-Based Statistical Areas (CBSAs)) established by the Office of Management and Budget (OMB). Hospitals are grouped by geographic location into either an urban labor market (that is, a metropolitan statistical area (MSA) or metropolitan division) or a statewide rural labor market (any area of a State that is not defined as urban). The current system establishes wage indexes for hospital labor market areas, not for individual hospitals. Many parties have argued that these definitions, in many instances, are not reflective of the true cost of labor for any given hospital, particularly for hospitals located on the periphery of labor markets or at labor market boundaries. Multiple exceptions and adjustments have been put into place in attempts to correct perceived inequities. However, many of these exceptions and adjustments may create or further exacerbate distortions in labor market values. The issue of ''cliffs,'' or significant differences in wage index values between proximate hospitals, can often be attributed to one hospital

benefiting from such an exception and adjustment when another hospital cannot.

On April 11, 2012, the Secretary submitted to Congress a report, ''Plan to Reform the Medicare Hospital Wage Index.'' This broad-based plan for reforming the hospital wage index included a fundamental change in the description and definition of labor market areas. The concept, referred to as the commuting based wage index (CBWI), would improve upon Medicare's existing wage index method by using commuting data to define hospital labor market areas. The CBWI is based on data on the number of hospital workers commuting from home to work to define a hospital's labor market. To derive the CBWI, commuting flows would be used to identify the specific areas (for example, zip code or census tracts) from which a hospital hires its workers and to determine the proportion of its workers hired from each area. A CBWI system could use either current hospital cost report data or other alternative sources, such as the Bureau of Labor Statistics (BLS) Occupational Employment Survey data, to calculate labor market area average wage values. While the current wage index system aggregates wage data within geographic CBSA-based areas where hospitals are located, the CBWI would aggregate wage data based upon where the hospital workers reside.

Once the hiring proportions by area and area wage levels are determined, the hospital's benchmark wage level would be calculated as the weighted average of these two elements. This value would then be divided by the national average. This calculation would result in a hospital-specific value, which reflects wage levels in the areas from which a hospital hires, accounting for variation in the proportion of workers hired from each area.

Using more precisely-defined labor markets, the CBWI values can vary for hospitals within the same CBSA or county and, thus, more precisely reflect wage differences within and across CBSA boundaries and address intra-area variation more precisely than the current system. Although the CBWI would allow wage index values to vary *within* a CBSA, the CBWI is less likely to produce large differences—or ''cliffs''—between wage index values for nearby hospitals in adjacent CBSA because nearby hospitals likely hire workers from areas in similar proportions.

Acumen found in its analysis that the CBWI system would more closely reflect hospitals' actual wages than the current CBSA-based system and the MedPAC proposal. As MedPAC suggested in its proposal, the exceptions and adjustments to the wage index system are the primary cause of the often significant ''cliffs'' between wage indexes of nearby hospitals. We believe the CBWI has the potential to reduce the need for exceptions and adjustments and further manipulation of wage index values (as is central to the MedPAC proposal) to prevent these ''cliffs'' between labor market areas.

The Report to Congress detailed several findings relevant to implementation of a CBWI:

- Because the CBWI accounts for specific differences in hospitals' geographic hiring patterns, it would yield wage index values that more closely correlate to actual labor costs than either the current wage index system (with or without geographic reclassification) or a system that attempts to reduce wage index differences across geographic boundaries, such as MedPAC's proposed wage index based on Bureau of Labor Statistics (BLS) data for health care industry workers.
- While a CBWI could be constructed with the most recent Census commuting data, were the CBWI to be adopted, a more up-to-date reporting system for collecting commuting data from hospitals would have to be established so that the wage index calculations would accurately reflect the commuting patterns of hospital employees. We believe that creating a system of more up-to-date commuting data could be achieved with a modest addition to the current reporting requirements.
- Concerns about a CBWI leading to hospitals altering hiring patterns and distorting labor markets do not appear to be worse than under the current system and could be managed with minimal policy adjustments.
- As current statutory provisions governing the Medicare wage index and exceptions to that wage index were designed for the current MSA-based wage index system, their applicability would need to be reviewed if a CBWI were to be adopted.
- The Medicare statute has traditionally applied payment changes in a budget neutral manner. If a CBWI were to be adopted in a budget neutrally manner, payments for some providers would increase while payments for other providers would decrease.

The Secretary was directed to ''consult with relevant affected parties'' during the development of the plan. In a special Medicare wage index open door forum held on April 12, 2011, hospital and hospital association representatives presented several concerns, which included issues with commuting data availability, the continuation of certain exceptions and adjustment policies, and the impacts of the CBWI upon other nonhospital payment systems. Several commenters expressed concern that a CBWI could encourage providers to alter or manipulate hiring practices in order to improve wage index calculations. However, based upon our findings and analysis, we believe it is dubious whether any alteration of a hospital's employment patterns would improve its competitive advantage over other hospitals that employ workers in the same area. We also share a concern expressed by multiple commenters regarding whether a CBWI should be applied to other nonhospital payment systems. Currently, several other payment systems are based upon the Medicare pre-reclassified hospital wage index. It is not clear whether it would be advantageous, or even possible, to apply a CBWI to these provider types.

2. Institute of Medicine (IOM) Study on Medicare's Approach to Measuring Geographic Variations in Hospitals' Wage Costs

In addition to submitting the aforementioned Report to Congress, in April 2010, the Secretary commissioned the Institute of Medicine (IOM) to evaluate Medicare's approach for measuring geographic variation in the wage costs faced by hospitals. The IOM's Phase I report, published in September 2011, is available via the Internet at: *http://iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.* In that report, IOM's Committee on Geographic Adjustment Factors in Medicare Payment proposed a set of recommendations for modifying the hospital wage index in both the method used in its construction and the data used in its calculation.

In constructing the wage index, the IOM recommends altering the current labor market definitions to account for the out-commuting patterns of health care workers who travel to a place of employment in an MSA other than the one in which they live. The IOM's recommendation is based on its theory that county-to-MSA commuting patterns reveal the degree of integration of labor markets across geographically drawn boundaries (that is, MSAs) and a commuting-based smoothing adjustment to the wage index would more accurately measure the market wage each hospital faces. The IOM model uses workers' out-commuting patterns to smooth wage index values for hospitals in different counties, similar

to the out-migration adjustment used in the current wage index system. The IOM also suggests that using out-commuting shares in the smoothing adjustment creates an index based on the wage levels of workers *living* in that area in which a hospital is located, as opposed to wage levels of workers *employed* in that area, as in the CBWI model. In calculating its smoothed wage index, the IOM uses the following four steps:

- Step 1—Compute a wage index for each MSA, adhering to Medicare's current approach for calculating the average hourly wage (AHW) paid by all IPPS hospitals located in the MSA (this step replicates the current pre-reclassification wage index).
- Step 2—Compute an area wage for each county equal to a weighted average of MSA-level AHWs, where the weight for each MSA measures the share of all hospital workers living in the county who commute to hospitals located in that MSA.
- Step 3—Assign all hospitals located in the county a hospital wage index value equal to the county area wage index.
- Step 4—Normalize wage indices to ensure budget neutrality, similar to the approach currently implemented by Medicare.

In addition, the IOM's wage index model uses hourly wage data from the BLS Occupational Employment Survey rather than from hospital cost reports. The IOM also recommends measuring hourly wages using data for all health care workers rather than only hospital workers and using a fuller set of occupations incorporated in the hospital wage index occupational mix adjustment. The IOM suggests that BLS data would reduce administrative burdens placed upon hospitals and, by broadening the array of reported occupations from what is currently covered in the hospital cost report, would achieve more accurate labor markets definitions and reduce year-to-year volatility. The IOM encourages CMS to establish an ongoing agreement with the BLS to use occupational survey data specific to health care workers to calculate average hourly wage values. The IOM suggests, for instance, that the 5-year American Community Survey is a potential source of the necessary commuting information, assuming CMS can arrange to obtain certain nonpublic ''micro-data'' from the BLS.

Preliminary findings demonstrate that the IOM hospital wage index method would result in the reduction in wage index ''cliffs,'' and would diminish the need to maintain current wage index exceptions and adjustments. The IOM also recommends that the hospital wage values should be applied to other nonhospital health care providers, shifting to a single measurement of geographic variation to be used in multiple Medicare provider payment systems. However, we believe that, by creating a wage index that measures the wage level only of workers who live near a hospital rather than of all workers who could potentially work at the hospital (including those who live far away from the hospital), IOM's approach may have some problematic implications. First, some of the wage information used by the IOM index is based on workers employed outside of the hospital's pertinent labor market. Second, the IOM index neglects market-relevant information regarding the wages of workers employed at the hospital who live outside the county of the hospital's location. If the in-commuting workers come from high wage areas, this information should contribute to increasing the hospital's wage index values. Likewise, if such workers live in low wage areas, they should contribute to decreasing the hospital's wage index values.

We are aware of numerous concerns from hospital and hospital association representatives regarding whether the BLS Occupational Employment Survey data is an acceptable source for hospital wage index calculations. (We refer readers to a discussion of the BLS occupational survey data in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43824 and 43825.) While the IOM proposal suggested a more refined use of BLS data than did the previous MedPAC recommendation, there may be significant operational challenges in accessing and compiling health care sector specific wage, occupational mix, and commuting data from the available datasets. Additional research would be required to determine whether the IOM recommendation for applying its hospital wage index to nonhospital providers would be appropriate.

To assist readers in understanding key concepts and differences in the wage index methodologies we discussed earlier in this section, we are presenting below a chart that includes a comparison of the CBWI, the IOM hospital wage index approaches, and MedPAC's recommendation from its June 2007 Report to Congress.

	Current wage index	IOM	MedPAC	CBWI
Labor Market Definition				
Labor Market Area	MSAs or Metropolitan Divisions/rural ''rest of State'' areas.	MSAs or Metropolitan Divisions/rural ''rest of State'' areas.	Blend of county and MSA labor market definitions (50/50).	Creates separate but linked labor-market for each hospital using small geographic areas (for example, zip codes).
Commuting Adjustment	Section 505 Out-Commuting Adjustment.	Adjusts hospitals' wage index values based on the out-commuting patterns of health care workers.	None	Uses in-commuting patterns relevant for individual hospitals to weight benchmark wages constructed for small geographic areas.

	Current wage index	IOM	MedPAC	CBWI
Other Adjustments	Multiple Reclassifications and/or Floors (for example, Frontier State floor, Lugar counties, MGCRB, and Section 508 reclassifications and special exceptions).	IOM proposes three smoothing specifications: (1) Apply to all counties; (2) Apply only to counties to which at least 10 percent of workers commute; (3) Apply only to counties to which at least 10 percent of workers commute and hospital wage index is higher than home-county hospital wage index.	Smoothing algorithm uses iterative process to eliminate large differences in index values across county boundaries.	None.
Measurement of Worker Wages				
Wage Data Source	Hospital cost reports	BLS Occupational Employment Survey.	BLS Occupational Employment Survey.	Any source of establishment wage data could potentially be used (for example, hospital cost reports, BLS Occupational Employment Survey).
Industry Sectors Used to Measure Wages.	Hospitals	Health care sector	All Industries (for example, hospitals, other health care, and nonhealth care sectors).	The CBWI could be implemented using any industry sector.
Occupational Mix	Occupational mix adjustment based on occupational categories of nurses reported on cost reports.	Occupational mix adjustment based on all occupations.	Occupational mix adjustment based on 30 occupations with the highest wage share in the hospital industry.	Occupational mix adjustment based on all occupations available in the wage data source selected.
Other Provider Settings				
Wage Index for Nonhospital Providers.	Pre-floor, pre-reclassification version of the current hospital wage index. A version of this index with an occupational mix adjustment has also been used for payments for other specialized hospital inpatient services.	Use identical hospital wage index methodology, except create an industry-specific occupational mix adjustment for each provider type.	No recommendation	Considerations include: (1) Collect commuting data for each provider type and apply CBWI; (2) Apply CBWI framework, but use hospital wage and commuting data; or (3) Measure using a weighted average of nearby-hospital CBWI values.

X. Proposed Quality Improvement Organization (QIO) Regulation Changes Related to Provider and Practitioner Medical Record Deadlines and Claims Denials

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51648 through 51649), we finalized changes to the utilization and quality control review regulation at 42 CFR 476.78 to require providers to submit medical records relating to services they have furnished in a shorter timeframe than the standard 30 calendar days in certain situations. Medical records must be submitted within 21 calendar days of serious reportable events or where other circumstances, as deemed by the Quality Improvement Organization (QIO), warrant earlier receipt of all required medical information. The changes were part of our effort to improve the QIO work, such as quality improvement assistance, beneficiary (or beneficiary representative) requested QIO quality of care reviews, and QIO medical necessity reviews to achieve the following three aims: (1) Improving individual care; (2) improving health care for populations; and (3) lowering costs through improvement efforts.

While these changes will enhance QIOs' efforts to effectively carry out their responsibilities in a timely manner, QIOs have historically experienced difficulty in obtaining medical information in a timely manner from providers and even more difficulty obtaining this information in a timely manner from practitioners. Without this information, QIOs are unable to carry out their review responsibilities. This is particularly problematic in cases in which Medicare beneficiaries may be awaiting a QIO's decision, for example, responses to complaints about the quality of care received. Although the regulations at 42 CFR Part 476 refer to practitioners' responsibilities in certain instances, § 476.78, which relates to the submission of medical information, addresses only the obligations of providers and not practitioners. No similar provisions exist within the QIO program regulations (that is, 42 CFR parts 475 through 480) that establish timeframes for the submission of medical information by practitioners. Moreover, § 476.90 addresses steps that

a QIO may take when providers or practitioners fail to cooperate with the QIO, including the QIO's authority to deny claims for the failure to respond to a QIO's request for information under paragraph (b) of § 476.90. However, § 476.90(b) limits the QIO's authority to deny claims to providers, and no similar provision exists for practitioners. In fact, a QIO's only recourse against practitioners is contained in § 476.90(a), which conveys a QIO's authority to recommend sanctions against practitioners, as well as providers, for the failure to present evidence of the medical necessity for or the quality of the care provided to a Medicare beneficiary. While recommending that sanctions be pursued against a practitioner is an option for QIOs, this is only appropriate when egregious circumstances exist, as described in 42 CFR 1004.30.

The responsibility of practitioners and providers to supply information to QIOs for use in completing their review activities is implicit throughout the QIO program statute. Most notably, section 1154(a)(7)(C) of the Act makes reference to the QIO's obligation to examine the pertinent records of any practitioner or provider of Medicare services if the QIO has the responsibility of reviewing those services. Section 1156(a) of the Act explicitly addresses the obligation of providers and practitioners to provide information to the QIO. It requires providers and practitioners to support the services or items they have furnished with evidence of their medical necessity and quality. Providers and practitioners must provide this evidence to the QIO in the form and fashion and at such time as may reasonably be required by a QIO in exercising its duties and responsibilities. A practitioner's or provider's failure to provide this evidence could result in the QIO reporting this failure to the Inspector General. One of the QIO's responsibilities, as described in section 1154(a)(2) of the Act, is to determine whether payment shall be made for Medicare services, based on its determination of whether a provider's or practitioner's services were reasonable and medically necessary, met professionally recognized quality standards, and/or were provided in the appropriate setting. It is not possible for a QIO to make a determination that services met these standards and that payment would be appropriate without the medical records it needs to conduct these reviews.

In light of the issues discussed above, in this proposed rule, we are proposing several changes to the regulations at §§ 476.1, 476.78, and 476.90 to more clearly convey the responsibilities of providers and practitioners in submitting medical information and to specify the QIO's authority should the information not be received.

- We are proposing to add a definition of ''providers'' under § 476.1 to clearly denote that certain requirements in Part 476 apply to health care facilities, institutions, and organizations involved in the delivery of health care services to Medicare beneficiaries.
- We are proposing to change the section heading of § 476.78 from ''Responsibilities of health care facilities'' to ''Responsibilities of providers and practitioners''. In addition, we are proposing to add references to ''practitioners'' in § 476.78(b)(2) so that the 21-day and 30-day timeframes for submittal of information apply equally to practitioners and providers. We also are proposing one minor technical change to § 476.78 that is unrelated to the application of timeframes to providers or practitioners. We are proposing to remove the sentence, ''QIOs pay providers paid under the prospective payment system for the costs of photocopying records required by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first-class postage for mailing the records to the QIO'', because it is merely a reference to paragraph (c) of § 476.78. Because the sentence does not provide substantive information, we believe it can be deleted without losing any of the necessary content of the paragraph.
- We are proposing changes to § 476.90 that will provide improved instructions to QIOs when attempting to resolve issues associated with practitioners and providers that fail to submit medical information within the timeframes set forth in § 476.78. These proposed changes include: Changing the section heading from ''Lack of cooperation by a health care facility or practitioner'' to ''Lack of cooperation by a provider or practitioner''; incorporating the broader term ''provider'' (as reflected in our proposed change to § 476.1) within § 476.90, as well as references to ''practitioners'', where appropriate. We note that we are proposing to add references to ''practitioners'' in § 476.90(a)(2) to denote that the QIO's authority includes the ability to make financial liability determinations for both providers and practitioners, and we are proposing to add the word ''may'' to clarify that the QIO has the discretion to report a provider's or practitioner's failure to provide evidence of the medical necessity or quality of care provided to the Inspector General. In addition, we are proposing modifications to § 476.90 (b) to denote that QIOs will also deny claims if practitioners fail to submit medical information as requested. We have based this proposed change on the fact that a QIO cannot make a determination about whether payment shall be made on the basis of its reviews, as described in section 1154(a)(2) of the Act, if the QIO does not have the medical records it needs to determine that payment would be appropriate. We also are proposing to add new language to § 476.90(b) to convey the right of providers and practitioners to request a reconsideration by the QIO of its decision to deny the claim based on the failure to receive the medical information, and that no further appeal rights exist beyond the QIO.
- We are proposing to make a technical correction to a cross-reference to ''§ 474.30(c)'' that appears in § 476.90(a)(1). This cross-reference is to the Office of Inspector General regulations that convey the obligations of providers and practitioners; these regulations are now located in 42 CFR 1004.10(c).

We are inviting public comment on our proposals, including the definition of ''providers'', the timeframes for practitioners and providers to follow in submitting medical information, the QIO's authority when medical information is not received, as well as the technical corrections.

XI. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS*. Data files and the cost for each file, if applicable, are listed below. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS–PUF) to cover the cost of the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2009 Medicare cost reports used to create the proposed FY 2013 prospective payment system wage index. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.L. of the preamble of this proposed rule.

Processing year	Wage data year	PPS fiscal year
2012	2009	2013
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Periods Available: FY 2007 through FY 2013 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the 2010 occupational mix survey data to be used to compute the occupational mix adjustment wage indexes. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.L. of the preamble of this proposed rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Period Available: FY 2013 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Period Available: FY 2013 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2013 IPPS Update.

5. FY 2012 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a historical list of Metropolitan Statistical Areas (MSAs).

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2013 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at: *http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp* and Compact Disc (CD).

File Cost: $100.00 per year.

7. Provider-Specific File

This file is a component of the PRICER program used in the fiscal intermediary's or the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at: *http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03_psf_text.asp*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 1985 through FY 2013.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay as published in the **Federal Register**. There are two versions of this file as published in the **Federal Register**.

- Notice of proposed rulemaking.
- Final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*

Periods Available: FY 2005 through FY 2013 IPPS Update

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital impatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the Federal Register. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking.
- Final rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage*.

Periods Available: FY 1994 through FY 2013 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2013 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-based Statistical Area (CBSA). The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2013 IPPS Update.

13. Hospital Readmissions Reduction Program File

This file contains information on the calculation of the Hospital Readmissions Reduction Program payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction, pneumonia and heart failure and the proxy readmissions payment adjustment for each provider included in the program.

The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register.**
- Final rule published in the **Federal Register**.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2013 IPPS Update.

For further information concerning these data tapes, contact the CMS Public Use Files Hotline at (410) 786–3691.

Commenters interested in discussing any data used in constructing this proposed rule should contact Nisha Bhat at (410) 786–5320.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of this proposed rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2014 must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold. We detailed the burden associated with this requirement in the September 7, 2001, IPPS final rule (66 FR 46902). As stated in that final rule, collection of the information for this requirement is conducted on an individual case-by-case basis. We believe the associated burden is thereby exempt from the PRA as stipulated under 5 CFR 1320.3(h)(6). Similarly, we also believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. In FYs 2008, 2009, 2010, 2011, 2012, and 2013, we received 1, 4, 5, 3, 3, and 5 applications, respectively.

3. ICRs for the Occupational Mix Adjustment to the Proposed FY 2013 Index (Hospital Wage Index Occupational Mix Survey)

Section II.F. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2013 wage index. While the preamble does not contain any new ICRs, it is important to note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; however, it is currently approved under OMB control number 0938–0907, with an expiration date of February 28, 2013.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.H.3. of the preamble of this proposed rule discusses proposed revisions to the wage index based on hospital redesignations. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index or standardized payment amounts and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. While this requirement is subject to the PRA, the associated burden was previously approved under OMB control number 0938–0573. However, the information collection expired on December 31, 2011. We are currently seeking to reinstate the information collection and, as required by the PRA, will announce public notice and comment periods in the **Federal Register** separate from this notice of proposed rulemaking.

5. ICRs for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed under section IV.I.4. of this preamble, are not subject to the Paperwork Reduction Act (44 U.S.C. Chapter 35), as stated in section 5506 of the Affordable Care Act.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a ''starter set'' of 10 quality measures. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. We are currently seeking reinstatement of the information collection previously approved under that control number. However, we will be combining the proposed information collection requirements discussed below and addressed in section VIII.A. of this preamble, with the Hospital IQR Program PRA package that was previously approved under 0938–1022. This proposed rule will serve as the required 60-day Federal Register notice to solicit public comments. We welcome public comments on both the plan to combine the PRA packages and the proposed information collection requirements in this proposed rule.

We added additional quality measures to the Hospital IQR Program and submitted an information collection request to OMB for approval. This expansion of the Hospital IQR measures was part of our implementation of section 5001(a) of the DRA. Section 1886(b)(3)(B)(viii)(III) of the Act, as added by section 5001(a) of the DRA, requires that the Secretary expand the ''starter set'' of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures ''that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings.'' The burden associated with these reporting requirements was previously approved under OMB control number 0938–1022.

For the FY 2015 payment determination, we intend to seek OMB approval for a revised information collection request using the same OMB control number (0938–1022). In the revised request, we are proposing to add one chart-abstracted measure (Elective Delivery Prior to 39 Weeks Gestation), one survey-based measure, and three claims-based measures. In addition, we are proposing to remove one chart-abstracted measure (SCIP–VTE–1: Surgery patients with recommended venous thromboembolism prophylaxis) and 16 claims-based measures.

In addition, in this request, for FY 2016 payment determinations, we are proposing to add one structural measure. We estimate that the proposed changes to our FY 2015 and FY 2016 payment determination measure set will result in a total collection burden to IPPS hospitals of approximately 6,273,199 hours per year.

With respect to the proposed new chart-abstracted measure for the FY 2015 payment determination, we are proposing to add the chart-abstracted measure, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. Hospitals would be required to submit data on patients who have elective vaginal deliveries or elective cesarean sections at >=37 and <39 weeks of gestation completed. We estimate that IPPS hospitals will incur an additional 117,474 burden hours resulting from the proposed addition of this measure. We estimate that hospitals will submit data on approximately 1,006,917 cases annually for this measure, and it will require, on average, 7 minutes to abstract the information from medical records for each case to calculate these measures.

The one proposed additional survey measure would be added to the existing HCAHPS survey. Burden for the HCAHPS data collection is currently approved through OMB control number 0938–0981.

The structural measure we are proposing for the FY 2016 payment determination, the Safe Surgery Checklist Use, would require hospitals to report their yes/no response regarding use of a safe surgery checklist. We estimate that it would take the 3,300 hospitals approximately 2 minutes each to answer this question each year, resulting in an estimated total increase of 110 hours for the total burden to hospitals each year.

We also are proposing to add three new claims-based measures for the FY 2015 payment determination. We do not believe that these claims-based measures would create any additional burden for hospitals because they would be collected and calculated by CMS based on the Medicare FFS claims the hospitals have already submitted to CMS.

We believe that the overall burden on hospitals will be reduced to some extent by the proposed removal of one chart abstracted measure, SCIP–VTE–1: Surgery Patients with Recommended Venous Thromboembolism Prophylaxis, beginning with the FY 2015 payment determination. In addition, in this proposed rule, beginning with the FY 2015 payment determination, we are proposing to remove 16 claims-based measures. We estimate that the proposed removal of the SCIP–VTE–1-measure will reduce the total burden to hospitals by a total of 150,000 hours.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section VIII.B. of this preamble, pursuant to section 1866(k) of the Act, for purposes of FY 2014 and each subsequent fiscal years, a hospital described in section 1886(d)(1)(B)(v) of the Act shall submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. To comply with the statutory mandate, we are implementing the PCHQR Program in our sustained efforts to improving the quality of care for inpatient cancer patients. It is our aim and goal to facilitate high quality of care in a manner that is effective and meaningful, while remaining mindful of reporting burden posed on the PCHs. Therefore, we intend to reduce and avoid duplicative reporting efforts, whenever possible, by leveraging existing infrastructure.

For the FY 2014 program year, we are proposing five NQF-endorsed quality measures developed by the CDC and the American College of Surgeons' Commission on Cancer (ACoS/CoC).

Measure steward	Quality measures
ACoS/CoC	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer (NQF#0223).

Measure steward	Quality measures
CDC	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer (NQF#0559). Adjuvant Hormonal Therapy (NQF#0220). National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF#0139). National Healthcare Safety Network (NHSN)Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF#0138).

We estimate that 11 PCHs will submit data on approximately 27,273 cases annually for these measures, and it will require, on average, 2.5 hours to abstract the information from medical records for each case to calculate these measures.

Although PCHs have not reported on quality measures to CMS, they have some familiarity with and experience in reporting of quality data. More specifically, out of the 11 existing PCHs, 10 are currently reporting the proposed cancer-specific measures to the ACoS/CoC. This equates to 91 percent of PCHs that already report the measures on a regular basis. Likewise, a majority of the PCHs have been submitting data to the CDC. We believe the fact that the majority of the PCHs have demonstrated the ability to report the measures indicates the proposed regulation do not significantly impact PCHs.

Furthermore, we estimate that reporting aggregated-level data through the CDC and the CMS contractor will not be costly to PCHs. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through these entities (CDC and the CMS contractor). We estimate that the annual hourly burden to each PCH for the collection, submission, and training of personnel for submitting all quality measures is approximately 6293.5 hours in a year for each PCH. The average hourly burden to each PCH is approximately 524 hours per month. This proposed rule would affect all PCHs participating in Medicare. The facilities would have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the Notice of Participation form. The anticipated burden to these providers consists of the following: (1) The initial registration with the CDC, CMS contractor, and CMS QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data to the CDC and the CMS contractor database by the PCH's representative.

We believe the fact that the majority of the PCHs have demonstrated the ability to report the measures indicates the proposed regulation do not significantly impact PCHs. We are proposing the following approach for data reporting. First, patient-level data would be submitted by the PCHs to the CDC for the proposed HAI measures and to the CMS contractor for the proposed cancer-specific measures. Second, the NHSN and CMS contractor will submit aggregated and calculated measure rates to CMS.

We are proposing to implement some procedural requirements to meet the statutory mandate by setting requirements and align with current quality reporting programs. These procedural requirements would involve submission of data to comply with the PCHQR Program requirement.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section VIII.C. of the preamble of this proposed rule, we discuss our proposal to add requirements for the FY 2015 Hospital VBP Program. Specifically, we are proposing to add two additional clinical process of care measures—AMI–10: Statin Prescribed at Discharge and SCIP–Inf-10: Surgery Patients with Perioperative Temperature Management—and two additional outcomes measures—an AHRQ Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are proposing to add a measure of Medicare Spending per Beneficiary in the Efficiency domain. All of these measures are required for the Hospital IQR program; therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

9. ICRs for the Long-Term Care Hospital Quality Reporting (LTCHQR) Program

The FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756) adopted three quality measures for the FY 2014 Payment Determination: (1) Urinary Catheter Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients (NQF#0138); (2) Central Line Catheter-Associated Blood Stream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients (NQF#0139); and (3) Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) (NQF #0678). The three measures finalized for the FY 2014 payment determination were NQF-endorsed at the time, although not for the LTCH setting. We also stated the NQF was expected to review some of these measures for applicability to the LTCH setting, and we anticipated this review may result in modifications to any such measures.

As part of its endorsement maintenance process, under NQF's Patient Safety Measures Project (*http://www.qualityforum.org/projects/patient_safety_measures.aspx*), the NQF reviewed the CAUTI and CLABSI measures previously adopted and expanded the scope of endorsement to include additional care settings, including LTCHs. The original NQF-endorsed numbers were retained for these two expanded measures, but the measures were retitled to reflect the expansion of the scope of endorsement. The NQF #0138 Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days measure is now titled as National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. The NQF #0139 (Central Line Catheter-Associated Blood Stream Infection [CLABSI] Rate for ICU and High Risk Nursery (HRN) Patients is now titled National Health Safety Network (NHSN) Central Line Associated Blood Stream Infection (CLABSI) Outcome Measure (*http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Patient_Safety_Measures.aspx*). These expanded measures allow for the calculation of standardized infection

ratio (SIR).[210,211,212,213] We are proposing that the CAUTI and CLABSI measures be adopted in their expanded form for the FY 2014 payment determination and all subsequent fiscal year payment determinations.

We also are proposing in the preamble of this proposed rule to retain the measure Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), adopted in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination for all subsequent fiscal year payment determinations. We further noted that the Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) measure is undergoing NQF review for expansion in the scope of endorsement to include additional care settings, including the LTCHs.

In addition, we are proposing five additional quality measures for use in the LTCHQR Program which would affect the FY 2016 LTCHQR Program payment determination. These measures are: (1) Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); (2) Percentage of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (short-stay) (NQF #0682); (3) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); (4) Ventilator Bundle (NQF #0302); and (5) Restraint Rate per 1000 Patient Days (not NQF-endorsed).

The information needed for the three proposed measures, NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure, NHSN Central line- associated Bloodstream Infection (CLABSI) Outcome Measure, and Influenza Vaccination Coverage among Healthcare Personnel, would be collected via the CDC/NHSN (*http://www.cdc.gov/nhsn/*). We are proposing that LTCHs report data on these measures according to measure specifications of these NQF-endorsed measures.

The NHSN is a secure, Internet-based surveillance system that is maintained and managed by CDC. Many LTCHs already submit data to the NHSN either voluntarily or as part of mandatory State reporting requirements for HAIs. There are currently 442 LTCHs in operation in the United States and, according to CDC, 80 of these LTCHs already submit HAI data to NHSN. For these LTCHs, we believe the burden related to complying with the requirements of the proposed quality reporting program would be reduced because of familiarity with the NHSN submission process.

Further, the initial setup and acclimation to the NHSN system will have already occurred through the implementation of the of the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and the NHSN Central Line- Associated Bloodstream Infection (CLABSI) Outcome Measure for the FY 2014 LTCHQR Program payment determination to the extent they are adopted in the FY 2013 IPPS/LTCH PPS final rule. Even though these measures have been recently reviewed by the NQF and expanded to post-acute care settings, including LTCHs, there has been no change in the way that the data for these measures is to be collected and reported to NHSN. Likewise, there has been no change in the registration and training requirements for providers that are new to the NHSN reporting system. In addition, LTCH providers will begin to use the NHSN system to report CAUTI and CLABSI data on October 1, 2012, to the extent they are adopted in the FY 2013 IPPS/LTCH PPS final rule. By the time that any new measures that are proposed above have been finalized and reporting of same begins, LTCH providers should be very familiar and comfortable with the NHSN reporting system. Thus, by that time, the additional burden related to the reporting of any additional measures should they be finalized in the FY 2013 IPPS/LTCH PPS final rule.

The burden associated with these proposed quality measures is the time and effort associated with collecting and submitting the data concerning CAUTI, CLABSI, and Influenza Vaccination Coverage among Healthcare Personnel to NHSN for LTCHs that are not currently reporting such data. As we have stated above, for LTCHs that already submit data regarding these measures to NHSN, we believe there should be little, if any, additional burden. For LTCHs that submit data to NHSN for other HAIs, but not data for these three proposed measures, there may be some added burden. However, we believe that this burden would be significantly decreased because these LTCHs will already be enrolled in the NHSN system for the submission of measures for the FY 2014 LTCHQR payment determination, provided the proposed CAUTI and CLABSI measures are finalized, and will be already familiar with the NHSN data submission process.

There are currently 442 LTCHs in the United States paid under the LTCH PPS. We estimate that each LTCH would submit approximately 12 NHSN submissions (6 CAUTI events and 6 CLABSI events) per month (144 events per LTCH annually). This equates to a total of approximately 63,648 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment would take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN database. Based on this estimate, we expect each LTCH would expend 300 minutes (5 hours) per month and 60 hours per year reporting to NHSN. Therefore, the total estimated annual hourly burden to all LTCHs in the United States for reporting to NHSN is 26,520 hours.

The estimated cost per submission is estimated at $12.07. These costs are estimated using an hourly wage for a registered nurse of $41.59 and a medical billing clerk/data entry person of $20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH provider would be $1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN would be $768,497 [214] While these proposed requirements would be subject to the Paperwork Reduction Act, we believe the associated burden hours are accounted for in the information collection request currently approved, OCN 0920–0666.

We analyzed the information collection requirements for the FY 2014 LTCHQR Program quality reporting measure ''Percent of Residents with Pressure Ulcers that are New or Worsened (NQF #0678)'' in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51781).

[210] Centers for Disease Control and Prevention. (2012, January). Central Line-Associated Bloodstream Infection (CLABSI) Event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

[211] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0139.*

[212] Centers for Disease Control and Prevention. (2012, January). Catheter Associated Urinary Tract Infection Event. Retrieved from: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

[213] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0138.*

[214] Nursing Time—24 hours @ $41.59 per hour = $998.16; $998.16 × 442 LTCHs = approximately $441,187.

Admin Time—36 hours @ $20.57 per hour = $740.52; $740.52 × 442 LTCHs = approximately $327,310.

TOTAL = $441,187 + $327,310 = $768,497.

With respect to the remaining four proposed measures, Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, Percentage of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (short-stay); Ventilator Bundle, and Restraint Rate per 1,000 Patient Days, we are proposing that we would post the specification for the measures, at a later date, on our Web site along with the specific data elements necessary to be collected. We are proposing to do so because, at this time, we have not completed development of the information collection instrument that LTCHs will use to submit the data for these measures. Because the forms are still under development, we cannot make a complete burden estimate at this time. We are proposing that reporting and submission of these four measures be incorporated into the existing data collection and submission framework, the LTCH CARE Data Set. This is the same data collection and submission framework that will be used by CMS to support providers for reporting on the Percent of Residents with Pressure Ulcers That Are New or Worsened measure.[215]

By building upon preexisting resources for data collection and submission, we intend to foster alignment between measures that helps to reduce the administrative burden related to data collection and submission. We anticipate that the initial setup and acclimation to the data collection by the LTCH CARE Data Set will have already occurred with the adoption of the Pressure Ulcer measure for the LTCHQR Program for the FY 2014 payment determination. Therefore, we believe the transition to reporting the four proposed measures via the LTCH CARE Data Set may be less burdensome.

The delivery of high quality care in the LTCH setting is imperative. We believe that collecting quality data on all patients in the LTCH setting supports CMS' mission to ensure quality care for Medicare beneficiaries. Collecting data on all patients provides the most robust and accurate reflection of quality in the LTCH setting.

At this time, we have not completed development of the information collection instrument that LTCHs would have to submit to comply with the aforementioned reporting requirements regarding the measures proposed for data collection by the LTCH CARE Data Set for the FY 2016 LTCHQR payment determination. Because the forms are still under development, we cannot make a complete burden estimate at this time. Once the forms are available, we will prepare and submit the required Paperwork Reduction Act (PRA) package which will fully set forth the anticipated burden to LTCH providers as a result of the new data items (questions) that need to be added to the LTCH CARE Data Set. The PRA process provides for the publication of two PRA notices in the **Federal Register** which are followed by 60 and 30 day comment periods respectively. The PRA notice and comment process is similar to that provided for with the proposed and final rule notice and comment process. Therefore, even if it is not possible, at this time, for CMS to provide all of the necessary burden estimate information related to the new measures that we are proposing to add to the LTCHQR Program, stakeholders will still be afforded opportunities to submit public comments in accordance with the PRA rules and guidelines.

10. ICRs for the Ambulatory Surgical Center (ASC) Quality Reporting Program

In section VIII.E. of the preamble of this proposed rule, we discuss the proposed requirements for the ASC Quality Reporting Program for payment determinations affecting CY 2014 and subsequent years. In section XIV.K. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement a quality reporting program for ASCs beginning with the CY 2014 payment determination. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554) for a detailed discussion of the ASC Quality Reporting Program collection of information requirements for the claims-based and structural measures for the CY 2014 and CY 2015 payment determinations.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal to consider an ASC to be participating in the ASC Quality Reporting Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the program on their CY 2012 claims relating to the finalized measures.

For the CY 2015 payment determination and subsequent payment determination years, we are proposing that once an ASC submits any quality measure data, it would be considered to be participating in the ASC Quality Reporting Program. Once an ASC submits quality measure data indicating its participation in the ASC Quality Reporting Program, in order to withdraw, an ASC must complete and submit an online form indicating that it is withdrawing from the quality reporting program.

For the CY 2015 payment determination and subsequent payment determination years, if the ASC submits quality measure data, there is no additional action required by the ASC to indicate participation in the program. The burden associated with the requirements to withdraw from the program is the time and effort associated with accessing, completing, and submitting the online form. Based on the number of hospitals that have withdrawn from the Hospital OQR Program over the past 4 years, we estimate that 2 ASCs would withdraw per year and that an ASC would expend 30 minutes to access and complete the form, for a total burden of 1 hour per year.

For the CY 2015 payment determination, we are proposing to require ASCs to identify and register a QualityNet administrator in order to set up accounts necessary to enter structural measure data. We estimate that, based upon previous experience with the Hospital OQR Program, it would take an ASC 10 hours to obtain, complete, and submit an application for a QualityNet administrator and then set up the necessary accounts for structural measure data entry. We estimate the total burden to meet these requirements to be 51,750 hours (10 hours × 5,175 ASCs). We previously discussed the burden associated with the data entry of structural measure information for the ASC Quality Reporting Program in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554).

We are proposing to adopt a process for an extension or waiver for submitting information required under the program due to extraordinary circumstances that are not within the ASC's control. We are proposing that an ASC would complete a request form that would be available on the QualityNet Web site, supply requested information, and submit the request. The burden associated with these requirements is the time and effort associated with gathering required information as well as accessing, completing, and submitting the form. Based on the number of hospitals that have submitted a request for an extension or waiver from the Hospital OQR Program over the past 4 years, we estimate that 1 ASC per

[215] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA Notice which appeared in the **Federal Register** on September 2, 2011 (Volume 76, Issue 171). The file number for the LTCH PRA package is CMS–10409.

year would request an extension or waiver and that an ASC would expend 2 hours to gather required information as well as access, complete, and submit the form, for a total burden of 2 hours per year.

We also are proposing a reconsideration process that would apply to the CY 2014 payment determination and subsequent payment determination years under the ASC Quality Reporting Program. While there is burden associated with an ASC filing a reconsideration request, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals.

We are requesting public comments on these information collection requirements.

11. ICRs for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of this proposed rule, we discuss the implementation of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

Historically, IPFs have not been required to report quality data to CMS. However, they have been required to report quality measures to other entities such as TJC or State survey and certification organizations. Therefore, although IPFs have not reported on quality measures to CMS, they have some familiarity with and experience in reporting of quality data. More specifically, out of the 1,741 existing IPFs, 450 are currently reporting the proposed measures to TJC. This equates to 26.02 percent of IPFs that already report the measures on a regular basis. The fact that over one-quarter of the IPFs have demonstrated the ability to report the measures indicates the proposed regulation would not significantly impact IPFs.

Furthermore, we estimate that reporting aggregated-level data on QualityNet will not be costly to IPFs. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection, submission, and training of personnel for submitting all quality measures is approximately 821 hours in a year for each IPF. The average hourly burden to each IPF is approximately 68 hours per month.

This proposed rule would affect all IPFs participating in Medicare. The facilities would have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the data. The anticipated burden to these providers consists of the following: (1) The initial registration of the facility with QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data into the QualityNet database by the IPF's representative.

This proposed rule would affect all IPFs that currently do not already report data to CMS. These facilities will have to register with CMS and take the proper training in order to be adequately prepared to use the CMS QualityNet System for data submission.

Those IPFs that already report quality measures to the TJC will be minimally affected because the abstraction methods, population, sampling, and reporting approaches are similarly adopted by CMS. Therefore, IPFs that report the proposed IPFQR Program quality measures will experience a minimum burden.

We are requesting public comments on these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–1588–P

Fax: (202) 395–6974; or

Email: *OIRA_submission@omb.eop.gov*

C. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''**DATES**'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 424

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), and sec. 124 of Public Law 106–113 (113 Stat. 1501A–332).

2. Section 412.1 is amended by adding new paragraphs (a)(5) and (a)(6) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(5) This part implements section 1886(q) of the Act, which provides that, effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions, under the Hospital Readmissions Reduction Program. This reduction will be made through an adjustment to the hospital's base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

(6) This part implements section 1886(o)(1)(B) of the Act, which directs the Secretary to begin to make value-based incentive payments under the Hospital Value-Based Purchasing Program to hospitals for discharges

occurring on or after October 1, 2012, through an adjustment to the base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

* * * * *

3. Section 412.64 is amended by—

a. Revising paragraph (d)(1)(iv).

b. Revising the introductory text of paragraph (h)(4).

c. Revising paragraph (h)(4)(v).

d. Adding a new paragraph (h)(4)(vi).

The revisions and addition read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(iv) For fiscal years 2012 and 2013, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage point for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2013, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology.

* * * * *

(v) The product determined under paragraph (h)(4)(iv) of this section is the minimum wage index value for the State, except as provided under paragraph (h)(4)(vi) of this section;

(vi) For discharges on or after October 1, 2012 and before October 1, 2013, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

(A) CMS estimates a percentage representing the average percentage increase in wage index for hospitals receiving the rural floor due to such floor.

(B) For each all-urban State, CMS makes a onetime determination of the lowest hospital wage index in the State (including all adjustments to the hospital's wage index, except for the rural floor, the rural floor budget neutrality, and the outmigration adjustment) and increases this wage index by the percentage determined under paragraph (h)(4)(vi)(A) of this section, the result of which establishes the alternative minimum wage index value for the State.

* * * * *

4. Section 412.92 is amended by—

a. Revising paragraph (b)(2)(i).

b. Adding paragraph (b)(2)(v).

b. Adding paragraph (b)(3)(iv).

The revision and additions read as follows:

§ 412.92 Special treatment: Sole community hospitals.

* * * * *

(b) * * *

(2) * * * (i) Sole community hospital status is effective 30 days after the date of CMS' written notification of approval, except as provided in paragraph (b)(2)(v) of this section.

* * * * *

(v) If a hospital that is classified as an MDH under § 412.108 applies for classification as a sole community hospital because its status under the MDH program expires with the expiration of the MDH program, and that hospital's sole community hospital status is approved, the effective date of approval of sole community hospital status is the day following the expiration date of the MDH program if the hospital—

(A) Applies for classification as a sole community hospital prior to 30 days before the expiration of the MDH program; and

(B) Requests that sole community hospital status be effective with the expiration of the MDH program.

(3) * * *

(iv) A sole community hospital must report to the fiscal intermediary or MAC any factor or information that could have affected its initial classification as a sole community hospital. If CMS determines that a sole community hospital has failed to comply with this requirement, CMS may cancel the hospital's classification as a sole community hospital effective with the date the hospital failed to meet the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

* * * * *

5. Section 412.105 is amended by revising paragraph (b)(4) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(b) * * *

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or inpatient hospice services.

* * * * *

6. Section 412.140 is amended by revising paragraphs (a)(3)(i), (b), and (d)(2) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Review (IQR) Program.

(a) * * *

(3) * * *

(i) A hospital that would like to participate in the program for the first time (and to which paragraph (a)(3)(ii) of this section does not apply), or that previously withdrew from the program and would now like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the calendar year preceding the first quarter of the calendar year in which data submission is required for any given fiscal year.

* * * * *

(b) *Withdrawal from the Hospital IQR Program.* A subsection (d) hospital may withdraw from the Hospital IQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital must submit the withdrawal form by May 15 prior to the start of the payment year affected. For example, if a hospital seeks to withdraw from the FY 2015 payment determination, the hospital must submit the withdrawal form to CMS by May 15, 2014.

* * * * *

(d) * * *

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves a passing score, as determined by CMS, on applicable measure sets.

* * * * *

7. Subpart I is added to read as follows:

SUBPART I—ADJUSTMENTS TO THE BASE OPERATING DRG PAYMENT AMOUNTS UNDER THE PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT OPERATING COSTS

Sec.
412.150 Basis and scope of subpart.

Payment Adjustments Under the Hospital Readmissions Reduction Program

412.152 Definitions for the Hospital Readmissions Reduction Program.
412.154 Payment adjustments under the Hospital Readmissions Reduction Program.
412.155–412.159 [Reserved]

Incentive Payments Under the Hospital Value-Based Purchasing Program

412.160 Definitions for the Hospital Value-Based Purchasing Program.
412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.
412.163 Process for posting hospital-specific performance information under the Hospital Value-Based Purchasing (VBP) Program.
412.164 Measures selection under the Hospital Value-Based Purchasing (VBP) Program.
412.165 Performance standards under the Hospital Value-Based Purchasing (VBP) Program.
412.166 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.
412.167 Appeal under the Hospital Value-Based Purchasing (VBP) Program.
412.168–412.169 [Reserved]

SUBPART I—ADJUSTMENTS TO THE BASE OPERATING DRG PAYMENT AMOUNTS UNDER THE PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT OPERATING COSTS

§ 412.150 Basis and scope of subpart.

(a) Section 1886(q) of the Act requires the Secretary to establish a Hospital Readmissions Reduction program, under which payments to applicable hospitals are reduced in order to account for certain excess readmissions, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Readmission Reductions Program are specified in §§ 412.152 and 412.154.

(b) Section 1886(o) of the Act requires the Secretary to establish a Value-Based Purchasing (VBP) Program for inpatient hospitals (Hospital VBP Program), which requires CMS to make value-based incentive payments to hospitals that meet performance standards for applicable performance periods, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Value-Based Purchasing Program are specified in §§ 412.160 through 412.167.

Payment Adjustments Under the Hospital Readmissions Reduction Program

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

As used in this section and in § 412.154, the following definitions apply:

Aggregate payments for all discharges is, for a hospital for the applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

Aggregate payments for excess readmissions is, for a hospital for the applicable period, the sum, for the applicable conditions, of the product for each applicable condition of:

(1) The base operating DRG payment amount for the hospital for the applicable period for such condition;

(2) The number of admissions for such condition for the hospital for the applicable period; and

(3) The excess readmission ratio for the hospital for the applicable period minus 1.

Applicable condition is a condition or procedure selected by the Secretary among conditions and procedures for which:

(1) Readmissions represent conditions or procedures that are high volume or high expenditures; and

(2) Measures of such readmissions have been endorsed by the entity with a contract under section 1890 and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).

Applicable hospital is a hospital described in section 1886(d)(1)(B) of the Act or a hospital in Maryland that is paid under section 1814(b)(3) of the Act and that, absent the waiver specified by section 1814(b)(3) of the Act, would have been paid under the hospital inpatient prospective payment system.

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program.

Base operating DRG payment amount is the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Value-Based Purchasing Program, as specified under § 412.162. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, and a low volume of discharges under § 412.101.

Excess readmissions ratio is a hospital-specific ratio for each applicable condition for an applicable period, which is the ratio (but not less than 1.0) of risk-adjusted readmissions based on actual readmissions for an applicable hospital for each applicable condition to the risk-adjusted expected readmissions for the applicable hospital for the applicable condition.

Floor adjustment factor is the value that the readmissions adjustment factor cannot be less than for a given fiscal year. The floor adjustment factor is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Readmission is the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period of 30 days from the date of such discharge.

Readmissions adjustment factor is equal to the greater of:

(1) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges; or

(2) The floor adjustment factor.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii).

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

(a) *Scope.* This section sets forth the requirements for determining the payment adjustments under the Hospital Readmissions Reduction Program for applicable hospitals to account for excess readmissions in the hospital.

(b) *Payment adjustment.* (1) *General.* To account for excess readmissions, except as provided for in paragraph (d) of this section, an applicable hospital's base operating DRG payment amount is adjusted for each discharge occurring during the fiscal year. The payment adjustment for each discharge is determined by subtracting the product of the base operating DRG payment amount (as defined in § 412.152) for such discharge by the hospital's readmission payment adjustment factor for the fiscal year (determined under paragraph (e) of this section) from the base operating DRG payment amount for such discharge.

(2) *Special treatment for sole community hospitals.* In the case of a sole community hospital that receives payments under § 412.92(d) based on the hospital-specific rate, the difference between the hospital-specific rate

payment and the Federal rate payment determined under subpart D of this part is not affected by this payment adjustment.

(c) *Methodology to calculate the readmissions payment adjustment factor.* A hospital's readmission payment adjustment factor is the higher of the ratio described in paragraph (c)(1) of this section or the floor adjustment factor set forth in paragraph (c)(2) of this section.

(1) *Ratio.* The ratio is equal to 1 minus the ratio of the aggregate payments for excess readmissions as defined in § 412.152 and the aggregate payments for all discharges as defined in § 412.152.

(2) *Floor adjustment factor.* The floor adjustment factor is:

(i) For FY 2013, 0.99;

(ii) For FY 2014, 0.98; and

(iii) For FY 2015 and subsequent fiscal years, 0.97.

(d) *Hospitals paid under section 1814(b)(3) of the Act (certain Maryland hospitals).* The Secretary will consider whether to exempt Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the provisions of section 1814(b)(3) of the Act, would be paid under section 1886(d) of the Act from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings for the Hospital Readmissions Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act.

(1) CMS will establish criteria for evaluation of Maryland's annual report to the Secretary to determine whether Maryland will be exempted from the program for a given fiscal year.

(2) Maryland's annual report to the Secretary and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually.

(e) *Limitations on review.* There is no administrative or judicial review under this subpart of the following:

(1) The determination of base operating DRG payment amounts.

(2) The methodology for determining the adjustment factor under paragraph (c) of this section, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges.

(3) The applicable period.

(4) The applicable conditions.

(f) *Reporting of hospital-specific information.* CMS will make information available to the public regarding readmissions rates of each applicable hospital (as defined in § 412.152) under the Hospital Readmissions Reduction Program.

(1) To ensure that an applicable hospital has the opportunity to review and submit corrections for its excess readmission ratios for the applicable conditions for a fiscal year that are used to determine its readmissions payment adjustment factor under paragraph (c) of this section, CMS will provide each applicable hospital with confidential hospital-specific reports and discharge level information used in the calculation of its excess readmission ratios.

(2) Applicable hospitals will have a period of 30 days after receipt of the information provided in paragraph (f)(1) of this section to review and submit corrections for the excess readmission ratios for each applicable condition that are used to calculate the readmissions payment adjustment factor under paragraph (c) of this section for the fiscal year.

(3) The administrative claims data used to calculate an applicable hospital's excess readmission ratios for the applicable conditions for a fiscal year are not subject to review and correction under paragraph (f)(1) of this section.

(4) CMS will post the excess readmission ratios for the applicable conditions for a fiscal year for each applicable hospital on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov*).

§§ 412.155–412.159 [Reserved]

Incentive Payments Under the Hospital Value-Based Purchasing Program

§ 412.160 Definitions for the Hospital Value-Based Purchasing Program.

As used in this section and in §§ 412.162 through 412.167:

Achievement threshold means the median performance level among all hospitals on a measure during the baseline period or performance period, as applicable, for each measure for a fiscal year.

Applicable percent means the following:

(1) For FY 2013, 1.0 percent;

(2) For FY 2014, 1.25 percent;

(3) For FY 2015, 1.50 percent;

(4) For FY 2016, 1.75 percent; and

(5) For FY 2017 and subsequent fiscal years, 2.0 percent.

Base operating DRG payment amount means the following:

(1) With respect to a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Readmissions Reduction Program, as specified under § 412.154. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101.

(2) With respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) or a sole community hospital that receives payments under § 412.92(d), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101. This amount also does not include the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part.

(3) With respect to a hospital that is paid under section 1814(b)(3) of the Act, the payment amount under section 1814(b)(3) of the Act.

Benchmark means the arithmetic mean of the top decile of performance among all hospitals on a measure during the baseline period or performance period, as applicable, for each measure for a fiscal year.

Cited for deficiencies that pose immediate jeopardy means that, during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least two surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction.

Domain means a category of quality measures given weighting for purposes of performance scoring as a component of the Total Performance Score.

Domain score means the points awarded to a hospital for scored measures in a domain.

Hospital means a hospital described in section 1886(d)(1)(B) of the Act, but does not include a hospital, with respect to a fiscal year, for which one or more of the following applies:

(1) The hospital is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act for the fiscal year;

(2) The hospital was cited for deficiencies that pose immediate jeopardy by the Secretary during the performance period for the fiscal year;

(3) There are not a minimum number of measures that apply to the hospital for the performance period for the fiscal year; or

(4) There are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

Immediate jeopardy has the same meaning as that term is defined in § 489.3 of this chapter.

Improvement threshold means an individual hospital's performance level on a measure during the baseline period for a fiscal year.

Performance period means the time period during which data are collected for the purpose of calculating hospital performance on measures under the Hospital VBP Program.

Performance standards are the levels of performance that hospitals must achieve in order to earn points under the Hospital VBP Program.

Total Performance Score means the numeric score ranging from 0 to 100 awarded to each hospital based on its performance under the Hospital VBP Program with respect to a fiscal year.

Value-based incentive payment percentage means the percentage of the total base operating DRG payment amount for each discharge that a hospital has earned, based on its Total Performance Score, the applicable percent, and the exchange function slope, with respect to a fiscal year.

Value-based payment adjustment factor is calculated by subtracting the applicable percent from the value-based incentive payment percentage, converting the result to a number, and adding one.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii).

§ 412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.

(a) *General.* If a hospital meets or exceeds the performance standards that apply to the Hospital VBP Program for a fiscal year, CMS will make value-based incentive payments to the hospital under the requirements and conditions specified in this section.

(b) *Value-based incentive payment amount.* (1) *Available amount.* The value-based incentive payment amount for a discharge is the portion of the payment amount that is attributable to the Hospital VBP Program. The total amount available for value based incentive payments to all hospitals is equal to the total amount of base-operating DRG payment reductions, as estimated by the Secretary, according to section 1886(o)(6)(C)(ii)(I) of the Act.

(2) *Calculation of the value-based incentive payment amount.* The value-based incentive payment is determined by multiplying the base operating DRG payment amount and the value-based incentive payment percentage.

(3) *Calculation of the he value-based incentive payment percentage.* The value-based incentive payment percentage is calculated as the product of: The applicable percent as specified in paragraph (d) of this section, the hospital's Total Performance Score divided by 100, and the exchange function slope.

(c) *Methodology to calculate the value-based incentive payment adjustment factor.* (1) *General.* The base operating DRG payment amount payment amount for each discharge is adjusted under the Hospital VBP Program by multiplying the base operating DRG payment amount by the value-based incentive payment adjustment factor.

(2) *Calculation Methodology.* The value-based incentive payment adjustment factor for each discharge is determined by subtracting the applicable percent as specified in paragraph (d) of this section from the value-based incentive payment percentage and then adding that difference to one.

(d) *Hospitals paid under section 1814 of the Act (Maryland hospitals).* (1) The Secretary may exempt Maryland hospitals from the requirements of the Hospital VBP Program for a fiscal year if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program.

(e) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount.

(2) The determination of the amount of funding available for value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act.

(3) The establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act.

(4) The measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act.

(5) The methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores.

(6) The validation methodology that is specified under section 1886(b)(3)(B)(viii)(XI) of the Act.

§ 412.163 Process for posting hospital-specific performance information under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will make information available to the public regarding the performance of each hospital (as defined in § 412.160(h) of the subpart) under the Hospital VBP Program.

(b) To ensure that a hospital has the opportunity to review and submit corrections for the information to be made public under this section, CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its performance with respect to each measure, condition, and domain, and the calculation of its Total Performance Score.

(c) Hospitals will have a period of 30 days after CMS provides the information specified in paragraph (b) of this section to review and submit corrections for the information.

(d) CMS will post the information specified in paragraph (b) for each hospital on the *Hospital Compare* Web site.

§ 412.164 Measures selection under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will select measures, other than measures of readmissions, for purposes of the Hospital VBP Program. Such measures will be a subset of the measures specified under section 1886(b)(3)(B)(viii) of the Act (the Hospital Inpatient Quality Reporting Program).

(b) CMS will post data on each measure on the *Hospital Compare* Web site for at least 1 year prior to the beginning of a performance period for the measure under the Hospital VBP Program.

§ 412.165 Performance standards under the Hospital Value-Based Purchasing (VBP) Program.

(a) *Points awarded based on hospital performance.* (1) CMS will award points to hospitals for performance on each measure for which the hospital reports the applicable minimum number of cases during the applicable performance period.

(2) CMS will award from 1 to 9 points for achievement to each hospital whose performance on a measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark for that measure.

(3) CMS will award from 0 to 9 points for improvement to each hospital whose performance on a measure during the applicable performance period exceeds the improvement threshold but is less than the benchmark for that measure.

(4) CMS will award 10 points to a hospital whose performance on a measure during the applicable performance period meets or exceeds the benchmark for that measure.

(b) [Reserved]

§ 412.166 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.

The hospital's Total Performance Score for a program year is calculated as follows:

(a) CMS will calculate a domain score for a hospital when it reports the minimum number of measures in the domain.

(b) CMS will sum all points awarded for each measure in a domain to calculate an unweighted domain score.

(c) CMS will normalize the domain scores to ensure that the domain score is expressed as a percentage of points earned out of 100.

(d) CMS will weight the domain scores with the finalized domain weights for each fiscal year.

(e) The sum of the weighted domain scores is the hospital's Total Performance Score for the fiscal year.

§ 412.167 Appeal under the Hospital Value-Based Purchasing (VBP) Program.

(a) A hospital may appeal the following issues:

(1) CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;

(2) Whether the achievement/improvement points were calculated correctly;

(3) Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;

(4) Whether CMS correctly calculated the domain scores, including the normalization calculation;

(5) Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;

(6) Whether CMS calculated the HCAHPS consistency points correctly;

(7) Whether the correct domain scores were used to calculate the Total Performance Score;

(8) Whether each domain was weighted properly;

(9) Whether the weighted domain scores were properly summed to arrive at the Total Performance Score; and,

(10) Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

(b) Appeals must be submitted within 30 days of CMS' decision to deny a corrections request under § 412.163 or within 30 days of the conclusion of the review and corrections period, as applicable, and must contain the following information:

(1) Hospital's CMS Certification Number (CCN).

(2) Hospital name.

(3) Hospital's basis for requesting an appeal. This must identify the hospital's specific reason(s) for appealing the hospital's Total Performance Score or performance assessment with respect to the performance standards.

(4) CEO contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

(5) QualityNet System Administrator contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

(c) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount.

(2) The determination of the amount of funding available for value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act.

(3) The establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act.

(4) The measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act.

(5) The methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores.

(6) The validation methodology that is specified under section 1886(b)(3)(B)(viii)(XI) of the Act.

§§ 412.168–412.169 [Reserved]

8. Section 412.424 is amended by adding a new paragraph (d)(1)(vi) to read as follows:

§ 412.424 Methodology for calculating the Federal per diem payment amount.

* * * * *

(d) * * *

(1) * * *

(vi) *Applicable percentage change for fiscal year 2014 payment determination and for subsequent years.* (A) In the case of an inpatient psychiatric facility that is paid under the prospective payment system in § 412.1(a)(2) that does not submit quality data to CMS, in the form and manner and at a time specified by CMS, the applicable annual update to a Federal standard rate is reduced by 2.0 percentage points.

(B) Any reduction in the applicable annual update to a Federal standard rate will apply only to the fiscal year involved and will not be taken into account in computing the annual payment update for a subsequent year.

* * * * *

9. Section 412.434 is added to subpart N to read as follows:

§ 412.434 Reconsideration and appeals procedures of Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program decisions.

(a) An inpatient psychiatric facility may request reconsideration of a decision by CMS that the inpatient psychiatric facility has not met the requirements of the IPFQR Program for a particular fiscal year. An inpatient psychiatric facility must submit a reconsideration request to CMS no later than 30 days from the date identified on the IPFQR Program Annual Payment Update Notification Letter provided to the inpatient psychiatric facility.

(b) A reconsideration request must contain the following information:

(1) The inpatient psychiatric facility's CMS Certification Number (CCN);

(2) The name of the inpatient psychiatric facility;

(3) Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet system administrator, including each individual's name, email address, telephone number, and physical mailing address;

(4) A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the inpatient psychiatric facility did not meet the requirements of the IPFQR Program;

(5) A detailed explanation of why the inpatient psychiatric facility believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year; and

(6) Any evidence that supports the inpatient psychiatric facility's reconsideration request, such as emails and other documents.

(c) An inpatient psychiatric facility that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board under part 405, subpart R of this chapter.

10. Section 412.523 is amended by—

a. Adding a new paragraph (c)(3)(ix).

b. Revising paragraph (d)(3).

The addition and revision read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(ix) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2012, and ending September 30, 2013.* (A) The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2012, and ending September 30, 2013, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 2.1 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(B) With respect to discharges occurring on or after October 1, 2012 and before December 29, 2012, payments are based on the standard Federal rate in paragraph (c)(3)(ix)(A) of this section without regard to the adjustment provided for under paragraph (d)(3)(ii) of this section.

* * * * *

(d) * * *

(3) (i) *General.* The Secretary reviews payments under this prospective payment system and may make a one-time prospective adjustment to the long-term care hospital prospective payment system rates no earlier than December 29, 2012, so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.

(ii) *Adjustment to the standard Federal rate.* The standard Federal rate determined in paragraph (c)(3) of this section is permanently reduced by 3.75 percent to account for the estimated difference between projected aggregate payments in FY 2003 made under the prospective payment system implemented under this subpart and the projected aggregate payments that would have been made in FY 2003 under Part 413 of this chapter without regard to the implementation of the prospective payment system implemented under this subpart, excluding the effects of sections 1886(b)(2)(E) and (b)(3)(J) of the Act. This adjustment is transitioned over 3 years beginning in FY 2013.

(iii) *Special rule for certain discharges occurring during FY 2013.* The adjustment applied under paragraph (d)(3)(ii) of this section is not applicable when making payments under this subpart for discharges occurring on or after October 1, 2012, and on or before December 28, 2012.

* * * * *

11. Section 412.529 is amended by revising paragraph (d)(4)(i)(C) to read as follows:

§ 412.529 Special payment provisions for short-stay outliers.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) The payment amount specified under paragraph (d)(4)(i)(B) of this section may not exceed the full amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system determined under paragraph (d)(4)(i)(A) of this section.

* * * * *

12. Section 412.534 is amended by—

a. In the following paragraphs, removing the date ''October 1, 2012'' and adding in its place the date ''October 1, 2013'':

1. Paragraph (c)(1) heading;
2. Paragraph (c)(1)(i);
3. Paragraph (c)(1)(ii);
4. Paragraph (c)(2) heading;
5. Paragraph (d)(1) heading;
6. Paragraph (d)(1)(i);
7. Paragraph (d)(2) heading;
8. Paragraph (e)(1) heading;
9. Paragraph (e)(1)(i); and
10. Paragraph (e)(2) heading.

b. Revising the heading of paragraph (c)(3).

c. Revising the heading of paragraph (d)(3).

d. Revising the heading of paragraph (e)(3).

e. Revising paragraph (h)(4).

f. Revising paragraph (h)(5).

The revisions read as follows:

§ 412.534 Special payment provisions for long-term care hospitals within hospitals and satellites of long-term care hospitals.

* * * * *

(c) * * *

(3) *For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.* * * *

(d) * * *

(3) *For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.* * * *

(e) * * *

(3*) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.* * * *

(h) * * *

(4) For a long-term care hospital described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f), the policies set forth in this paragraph (h) and in § 412.536 do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on and after October 1, 2012 and before October 1, 2013.

(5) For a long-term care hospital or satellite facility that, as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location, the policies set forth in this paragraph (h) and in § 412.536 of this part do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.

13. Section 412.536 is amended by revising the introductory text of paragraph (a)(2) to read as follows:

§ 412.536 Special payment provisions for long-term care hospitals and satellites of long-term care hospitals that discharged Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital.

(a) * * *

(2) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013, the policies set forth in this section are not applicable to discharges from:

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

14. The authority citation for Part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

15. Section 413.24 is amended by revising paragraph (a) to read as follows:

§ 413.24 Adequate cost data and cost finding.

(a) *Principle.* Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting, except for—

(1) Governmental institutions which operate on a cash basis method of accounting. Cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(2) Costs of qualified defined benefit pension plans shall be reported on a cash basis method of accounting, as described at § 413.100(c)(2)(vii)(D) for cost reporting periods beginning on or after October 1, 2011.

* * * * *

16. Section 413.79 is amended by—

a. Revising paragraph (e)(1).

b. Revising paragraph (f)(7)(i)(B).

c. Redesignating paragraphs (n)(2)(ii) and (n)(2)(iii) as paragraphs (n)(2)(iii) and paragraph (n)(2)(iv), respectively.

d. Adding new paragraph (n)(2)(ii).

e. Revising redesignated paragraphs (n)(2)(iii) and (n)(2)(iv).

The revisions and addition read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(e) * * *

(1) If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it establishes a new medical residency training program on or after January 1, 1995, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted based on the product of the highest number of FTE residents in any program year during the third year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program. If a hospital that had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, begins training residents in a new program for the first time on or after October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted based on the product of the highest number of FTE residents in any program year during the fifth academic year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program.

(i) If the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective hospital's cap is equal to the product of the highest number of FTE residents in any program year during the third year of the first program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program and the number of years the residents are training at each respective hospital. If a hospital begins training residents in a new program for the first time on or after October 1, 2012, and if the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective new teaching hospital's cap is equal to the product of two amounts. The first amount is the product of the highest total number of FTE residents in any program year during the fifth year of the first program's existence at all of the participating hospitals involved and the number of years in which residents are expected to complete the program, based on the minimum accredited length for the type of program. The second amount is the ratio of the number of FTE residents in the new program that the hospital may count over the entire 5-year period to the total number of FTE residents that all of the participating hospitals may count over the entire 5-year period.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program(s), the hospital's cap may be adjusted during each of the first 3 years of the hospital's new residency program using the actual number of residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year. If a hospital begins training residents in a new program for the first time on or after October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the sixth year of the hospital's residency program(s), the hospital's cap may be adjusted during each of the first 5 years of the hospital's new residency program using the actual number of FTE residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(iii) Except for rural hospitals, the cap will not be adjusted for new programs established more than 3 years after the first program begins training residents. If a hospital begins training residents in a new program for the first time on or after October 1, 2012, except for rural hospitals, the cap will not be adjusted for new programs established more than 5 years after the first program begins training residents.

(iv) Effective for affiliation agreements entered into on or after October 1, 2005, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(v) A rural hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME

affiliated group for purposes of establishing an aggregate FTE cap.

* * * * *

(f) * * *

(7) * * *

(i) * * *

(B) Specify the effective period of the emergency Medicare GME affiliation agreement (which must, in any event, terminate at the conclusion of four academic years following the academic year in which the section 1135 emergency period began).

* * * * *

(n) * * *

(2) * * *

(ii) A hospital that receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section must fill at least half of its section 5503 slots in at least one of the following timeframes or lose its section 5503 slots under paragraph (n)(2)(iv) of this section: Its first 12-month cost reporting period of the 5-year period; and/or its second 12-month cost reporting period of the 5-year period; and/or its third 12-month cost reporting period of the 5-year period. Such a hospital that receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section also must fill all of the slots it received by its final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016, or under paragraph (n)(2)(iv) of this section, lose all of its section 5503 slots after June 30, 2016.

(iii) CMS may determine whether a hospital has met the requirements under paragraphs (n)(2)(i) and (n)(2)(ii) of this section during the 5-year period of July 1, 2011, through June 30, 2016, in such manner and at such time as CMS determines appropriate, including at the end of such 5-year period.

(iv) In a case where the Medicare contractor determines that a hospital did not meet the requirements under paragraphs (n)(2)(i) and (n)(2)(ii) of this section in a cost reporting period within the 5-year time period, the Medicare contractor will reduce the otherwise applicable FTE resident cap of the hospital by the amount by which such limit was increased under paragraph (n)(1) of this section from the earliest cost reporting period that is reopenable in which it would be determined that the hospital did not meet the requirements.

* * * * *

17. Section 413.100 is amended by adding a new paragraph (c)(2)(vii)(D) to read as follows:

§ 413.100 Special treatment of certain accrued costs.

* * * * *

(c) * * *

(2) * * *

(vii) * * *

(D) Exception: Qualified defined benefit pension plans, which are funded deferred compensation arrangements, shall be reported on a cash accounting basis as follows:

(1) The allowable pension cost shall be equal to the amount of actual pension contributions funded during the hospital's current Medicare cost reporting period, plus any contributions funded in a prior period and carried forward, subject to the limit under paragraph (c)(2)(vii)(D)(2) of this section.

(2) Except as provided in paragraph (c)(2)(vii)(D)(3) of this section, the allowable pension cost shall not exceed 150 percent of the average contribution(s) funded during the three consecutive Medicare cost reporting periods that produce the highest average contribution(s), out of the five most recent Medicare cost reporting periods (ending with the current cost reporting period). Contributions in excess of the limit may be carried forward to future period(s). In the case of a newly adopted pension plan, the 5-year look-back period and/or the 3-year averaging period will be limited to the number of cost reporting periods the provider sponsored a qualified defined benefit pension plan.

(3) A waiver of the limit imposed under paragraph (c)(2)(vii)(D)(2) of this section may be granted for a specific Medicare cost reporting period for all or a portion of the contributions in excess of the limit imposed under paragraph (c)(2)(vii)(D)(2) of this section if it is determined that such excess costs are reasonable and necessary for that period.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

18. The authority citation for Part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

19. Section 424.30 is revised to read as follows:

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by an MA organization, or through cost settlement with a health maintenance organization (HMO), a competitive medical plan (CMP), a health care prepayment plan (HCPP), or a demonstration. However, claims must be filed by hospitals seeking IME payment under § 412.105(g) of this chapter, and/or direct GME payment under § 413.76(c) of this chapter, and/or nursing or allied health education payment under § 413.87 of this chapter associated with services furnished on a prepaid capitation basis by an MA organization. Hospitals that must report patient data for services furnished on a prepaid capitation basis by an MA organization, or through cost settlement with a health maintenance organization (HMO), a competitive medical plan (CMP), a health care prepayment plan (HCCP), or a demonstration, for purposes of the DSH payment adjustment under § 412.106 of this chapter are required to file claims by submitting no pay bills for such patients. Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

20. The authority citation for Part 476 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

21. Section 476.1 is amended by adding a definition of ''Provider'' in alphabetical order, to read as follows:

§ 476.1 Definitions.

* * * * *

Provider means a health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part under Title XVIII of the Act.

* * * * *

22. Section 476.78 is amended by revising the section heading and the introductory text of paragraph (b)(2) to read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) Providers and practitioners must provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. When the QIO does postadmission, preprocedure review,

the provider must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers and practitioners must—

* * * * *

23. Section 476.90 is revised to read as follows:

§ 476.90 Lack of cooperation by a provider or practitioner.

(a) If a provider or practitioner refuses to allow a QIO to enter and perform the duties and functions required under its contract with CMS, the QIO may—

(1) Determine that the provider or practitioner has failed to comply with the requirements of 42 CFR 1004.10(c) and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the provider or practitioner, and may report the matter to the HHS Inspector General.

(b) If a QIO gives a provider or practitioner sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the provider or practitioner does not respond in a timely manner, the QIO will deny the claim. A provider or practitioner may request that the QIO reconsider its decision to deny the claim. No further appeal rights are available.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

24. The authority citation for Part 489 is revised to read as follows:

Authority: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869, 1871 and section 1886(o) of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, 1395hh, and 1395ww(o)).

25. Section 489.5 is added to read as follows:

§ 489.5 Definitions for purposes of the Hospital Value-Based Purchasing Program.

For purposes of the Hospital Value-Based Purchasing Program established under section 1886(o) of the Act—

(a) *Cited for deficiencies that pose immediate jeopardy* means that, during the applicable performance period, the hospital had more than one survey by the State survey agency for which it was cited for an immediate jeopardy on the Form CMS 2567, Statement of Deficiencies and Plan of Correction.

(b) *Immediate jeopardy* has the same meaning as the definition at § 489.3.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance)

Dated: April 2, 2012.

Marilyn Tavenner

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 13, 2012,

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Proposed Schedule of Standardized Amounts, Update Factors, and Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2012 and Proposed Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2012

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2013 for acute care hospitals. We also are setting forth the proposed rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS for FY 2013. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are proposing the rate-of-increase percentages for updating the target amounts for certain hospitals excluded from the IPPS that are effective for cost reporting periods beginning on or after October 1, 2012.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that would be applicable to Medicare LTCHs for FY 2013.

In general, except for SCHs and hospitals located in Puerto Rico, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge.

We note that, as discussed in section IV.G. of the preamble of this proposed rule, section 3124 of the Affordable Care Act extended the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). (Under prior law, the MDH program was to be in effect through the end of FY 2011 only.) Therefore, due to the expiration of the MDH program beginning with FY 2013, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2013.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2013. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2013. In section IV. of this Addendum, we are setting forth our proposed changes for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2013. In section V. of this Addendum, we are proposing to make changes in the determination of the standard Federal rate for LTCHs under the LTCH PPS for FY 2013. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the Internet.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2013

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth at § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth at §§ 412.211 and 412.212. Below we discuss the factors used for determining the proposed prospective payment rates for FY 2013.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts and Puerto Rico-specific standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act.
- Proposed updates of 2.1 percent for all areas (that is, the FY 2013 estimate of the

market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for multifactor productivity and less 0.1 percentage point), as required by section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. For hospitals that fail to submit data, in a form and manner, and at the time, specified by the Secretary relating to the quality of inpatient care furnished by the hospital, pursuant to section 1886(b)(3)(B)(viii) of the Act, the proposed update is 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.8 percentage point for multifactor productivity, and less 0.1 percentage point).

- A proposed update of 2.1 percent to the Puerto Rico-specific standardized amount (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for multifactor productivity and less 0.1 percentage point), in accordance with section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Public Law 108–173, which sets the update to the Puerto Rico-specific standardized amount equal to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62 percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for in section 1886(d)(8)(D) of the Act, by removing the FY 2012 budget neutrality factor and applying a revised factor.
- An adjustment to ensure the effects of the rural community hospital demonstration required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration for an additional 5 years are budget neutral, as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2012 outlier offset and apply an offset for FY 2013, as provided for in section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble to this proposed rule, an adjustment to meet the requirements of sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts to offset the estimated amount of the increase in aggregate payments (including interest) due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008, FY 2009. We are also proposing an adjustment to the standardized amounts to offset the estimated amount of the increase in aggregate payments) due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2010.

Beginning in FY 2008, we applied the budget neutrality adjustment for the rural floor to the hospital wage indices rather than the standardized amount. As we did for FY 2012, for FY 2013, we are proposing to continue to apply the rural floor budget neutrality adjustment to hospital wage indices rather than the standardized amount. Consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment on the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the proposed FY 2013 wage index for the rural floor. We note that, as finalized in the FY 2012 IPPS/LTCH PPS final rule, we extended the imputed floor through FY 2013 (76 FR 51593). Therefore, for this proposed rule, we are continuing to include the imputed floor in calculating the uniform, national rural floor budget neutrality adjustment to the wage indices. Thus, the imputed floor is reflected in the proposed FY 2013 wage index. Additionally, while we are proposing an alternative temporary methodology for computing the imputed floor index in section II.G.2. of the preamble of this proposed rule, we did not include this proposed alternative in our calculation of rural floor budget neutrality because of its negligible impact, although we intend to include it in the calculation if the policy is finalized.

We note that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51788 through 51790), we finalized an adjustment of 1.1 percent to the standardized amount (that is, a factor of 1.011) in light of the Cape Cod decision. The adjustment is a one-time permanent adjustment that is left permanently on the standardized amount.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. For Puerto Rico hospitals, the Puerto Rico-specific standardized amount is based on per discharge averages of adjusted target amounts from a base period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d)(9) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS. The September 1, 1987 final rule (52 FR 33043 and 33066) contains a detailed explanation of how the target amounts were determined and how they are used in computing the Puerto Rico rates.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

In accordance with section 1886(d)(3)(E) of the Act, the Secretary estimates, from time-to-time, the proportion of hospitals' costs that are attributable to wages and wage-related costs. In general, the standardized amount is divided into labor-related and nonlabor-related amounts; only the proportion considered to be the labor-related amount is adjusted by the wage index. Section 1886(d)(3)(E) of the Act requires that 62 percent of the standardized amount be adjusted by the wage index, unless doing so would result in lower payments to a hospital than would otherwise be made. (Section 1886(d)(9)(C)(iv)(II) of the Act extends this provision to the labor-related share for hospitals located in Puerto Rico.)

For FY 2013, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012, for the national standardized amounts and 62.1 percent for the Puerto Rico-specific standardized amount. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indices are greater than 1.0000, we are proposing to apply the wage index to a labor-related share of 68.8 percent of the national standardized amount. For FY 2013, all Puerto Rico hospitals have a wage index less than 1.0. Therefore, the national labor-related share will always be 62 percent because the wage index for all Puerto Rico hospitals is less than 1.0.

For hospitals located in Puerto Rico, we are applying a labor-related share of 62.1 percent if its Puerto Rico-specific wage index is greater than 1.0000. For hospitals located in Puerto Rico whose Puerto-Rico specific wage index values are less than or equal to 1.0000, we are applying a labor share of 62 percent.

The proposed standardized amounts for operating costs appear in Table 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via Internet.

2. Computing the Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are proposing to calculate the FY 2013 national and Puerto Rico standardized amounts irrespective of whether a hospital is located in an urban or rural location.

3. Updating the Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. As discussed in section IV.H. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the proposed FY 2013 applicable percentage increase (which is based on the first quarter 2012 forecast of the FY 2006-based IPPS market basket) by the multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2013) of 0.8 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) first quarter 2012 forecast. In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are further proposing to update the standardized amount for FY 2013 by the estimated market basket percentage increase less 0.1 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of Act, as added and amended by sections 3401(a) and 10319(a) the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services. Based on IGI's 2012 first quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the most recent forecast of the hospital market basket increase for FY 2013 is 3.0 percent. Thus, for FY 2013, the proposed update to the average standardized amount is 2.1 percent for hospitals in all areas (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for multifactor productivity and less 0.1 percentage point). For hospitals that do not submit quality data pursuant to section 1886(b)(3)(B)(viii) of the Act, the estimated proposed update to the operating standardized amount is 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the IQR program, less an adjustment of 0.8 percentage point for multifactor productivity, and less 0.1 percentage point) The proposed standardized amounts in Tables 1A through 1C that are published in section VI. of this Addendum and available via the Internet reflect these differential amounts.

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the proposed update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 2.1 percent.

Although the update factors for FY 2013 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2013 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our proposed recommendations in the Federal Register for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are proposing to adjust the FY 2013 standardized amount to remove the effects of the FY 2012 geographic reclassifications and outlier payments before applying the proposed FY 2013 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2013 payment policies.

We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to DRG classifications, recalibration of the DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

In order to appropriately estimate aggregate payments in our modeling, we make several inclusions and exclusions so that the appropriate universe of claims and charges are included. We discuss IME Medicare Advantage payment amounts, fee-for-service only claims, and charges for antihemophilic blood factor and organ acquisition below.

First, consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer the reader to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

Second, consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is a fee-for-service claim).

Third, consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422–50423), we examined the MedPAR and removed pharmacy charges for antihemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also removed organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

Section 3021 of the Affordable Care Act, codified at section 1115A of the Social Security Act, authorizes CMS to test innovative payment and service delivery models with the goal of reducing Medicare program expenditures while preserving or enhancing the quality of care furnished to individuals. Because initiatives established under this authority could result in IPPS hospitals receiving a payment different from what they otherwise would receive under the IPPS, we believe it is important to identify how these initiatives are addressed in the context of our budget neutrality calculations.

The Bundled Payments for Care Improvement (BPCI) initiative, developed by CMS' Center for Medicare and Medicaid Innovation under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), will test four payment models that link payments for multiple services during an episode of care. On August 23, 2011, CMS invited providers to apply to help develop and test four models of bundling payments under the BPCI. We refer the reader to section IV.H.4. of the preamble to this proposed rule for a discussion on the BPCI initiative. We note that under Models 1, 2, and 4, participating IPPS hospitals could receive a payment for all or selected IPPS claims under the BPCI that differs from payments they would otherwise receive under the IPPS. We also note that Model 3 addresses payments for related readmissions and postacute care services. Therefore, we believe it is not necessary to propose to address the treatment of any data for participating hospitals in Model 3.

For purposes of computing the budget neutrality calculations to compute the average standardized amount, we intend to include all applicable data from subsection (d) hospitals participating in BPCI models 1,

2, and 4 in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS–DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis). In essence, we would continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these three bundled payment models (that is, we would treat these hospitals as if they are not be participating in Model 1, Model 2, or Model 4 under the BPCI initiative). We believe it is appropriate to include all applicable data from these subsection(d) hospitals in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act (in addition to the reconciliation payment the hospital may receive under Model 2 of the BPCI initiative). Moreover, the Secretary has the authority to make appropriate adjustments for payment amounts at section 1886(d)(5)(I)(i) of the Act to include all applicable data from these ''subsection(d)'' hospitals in our IPPS ratesetting calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS short term acute care hospitals and their data within the IPPS ratesetting calculations since excluding these hospitals would diminish the number of providers used to determine the IPPS rates which could cause fluctuations to the IPPS rates and could produce instability to the IPPS rates.

The Affordable Care Act established the Hospital Readmissions Reduction Program and the Hospital Value-Based Purchasing Program which adjust payments to certain IPPS hospitals beginning with discharges on or after October 1, 2012. Because the adjustments made under these programs affect the estimation of aggregate IPPS payments, we believe it is appropriate to include adjustments for these programs within our budget neutrality calculations. We discuss the treatment of these two programs in the context of budget neutrality adjustments below.

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added a new subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the ''Hospital Readmissions Reduction Program'' effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Under the Hospital Readmissions Reduction Program at section 1886(q) of the Act, payments for discharges from an ''applicable hospital'' will be in an amount equal to the product of the ''base operating DRG payment amount'' and an ''adjustment factor'' that accounts for excess readmissions for the hospital for the fiscal year, for discharges beginning on October 1, 2012. (The statute also specifies that hospitals that receive any applicable add-on payments for IME, DSH, outliers and low-volume hospitals provided for under sections 1886(d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of the Act, respectively, are not affected by the adjustment for excess readmissions under the Hospital Readmissions Reduction Program.) In other words, payment under section 1886(q) is the base operating DRG payment amount multiplied by the adjustment factor, in addition to any outliers, IME, DSH, or low-volume payment adjustment the hospital may otherwise receive. We refer readers to section IV.A. of the preamble of this proposed rule for full details of our proposal implementing the Hospital Readmissions Reduction Program for FY 2013, including definitions of the ''base operating DRG payment amount.'' Under current law, the Hospital Readmissions Reduction Program under section 1886(q) of the Act is not budget neutral.

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year to payments for hospital discharges occurring on or after October 1, 2012. As specified under section 1886(o)(7)(B)(i) of the Act, the cost of these value-based incentive payments are funded by a reduction applied to each eligible hospital's base-operating DRG payment amount, for each discharge occurring in the fiscal year, beginning with FY 2013. For FY 2013, the reduction amount is equal to 1.00 percent, As required by section 1886(o)(7)(A) of the Act, the total amount of allocated funds available for value-based incentive payments is equal to the total amount of estimated base-operating DRG payment reductions (that is, 1.0 percent of eligible hospitals' base-operating DRG payment amount for FY 2013). We refer the reader to section VIII.C. of the preamble of this proposed rule for full details of our proposal implementing the Hospital VBP Program for FY 2013, including definitions of the ''base operating DRG payment amount.''

Unlike the Hospital Readmissions Reduction Program (where an adjustment factor is applied to reduce the base operating DRG payment amount for excess readmissions), the Hospital VBP Program has no effect on overall payments. As mentioned above, for FY 2013, the funding pool for value-based incentive payments is 1.0 percent of eligible hospitals' base-operating DRG payment which is equal to the total amount of estimated base-operating DRG payment reductions. In other words, the funding pool that CMS sets aside for the Hospital VBP Program is then equally redistributed by applying the hospital VBP adjustment. However, both the hospital readmissions payment adjustment (reduction) and the hospital VBP adjustment (redistribution) are applied on a claim by claim basis by adjusting, as applicable, the base operating DRG payment amount for individual IPPS hospitals which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations. For example, when we calculate the budget neutrality factor for DRG reclassification and recalibration of the relative weights, we compare (section II.4.a. of this Addendum contains for full details) aggregate payments estimated using the prior year's GROUPER and weights to estimated payments using the new grouper and weights. Other factors, such as the DSH and IME payment adjustments, are the same on both sides of the comparison because we are only seeking to ensure that aggregate payments do not increase or decrease as a result of the proposed changes of DRG reclassification and recalibration. In order to properly sum aggregate payments on each side of the comparison, we would need to apply the hospital readmissions payment adjustment and the hospital VBP adjustment on each side of the comparison. Therefore, to assure that aggregate payments are estimated correctly in light of the effects of the Hospital Readmissions Reduction Program and Hospital VBP Program, we are proposing that we would apply the readmissions payment adjustment and the Hospital VBP payment adjustment on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For this proposed rule, for the purpose of modeling the proposed aggregate payments for excess readmissions and the proposed readmissions adjustment factors, we are using excess readmission ratios for the applicable hospitals from the 3-year period of July 1, 2007 to June 30, 2010 (the 3-year period preceding the FY 2013 ''applicable period'' of July 1, 2008 to June 30, 2011 that was finalized in last year's rulemaking (76 FR 51671 through 51672), because the underlying data from this period have already be available to the public on the Hospital Compare Web site (as of July 2011). The data from the 3-year applicable period of July 1, 2008 to June 30, 2011, for FY 2013 have not been through the review and correction process required by section 1886(q)(6) of the Act (as proposed in section IV.A.3.d. of the preamble of this proposed rule). For the final rule, we intend to use excess readmission ratios based on admissions for the finalized applicable period of July 1, 2008 to June 30, 2011, to calculate the aggregate payments for excess readmissions and ultimately to calculate the readmissions payment adjustment factors, as applicable hospitals will have had the opportunity to review and correct these data before the data are made public under our proposal set forth in this rule regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act.

a. Proposed Recalibration of DRG Weights and Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.H. of the preamble of this proposed rule, we normalized the recalibrated DRG weights by an adjustment factor so that the average case weight after recalibration is equal to the average case weight prior to recalibration. However, equating the average

case weight after recalibration to the average case weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with indices less than or equal to 1.0 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2013, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.F. of the preamble of this proposed rule.

For FY 2013, to comply with the requirement that DRG reclassification and recalibration of the relative weights be budget neutral for the Puerto Rico standardized amount and the hospital-specific rates, we used FY 2011 discharge data to simulate payments and compared aggregate payments using the FY 2012 labor-related share percentages, the FY 2012 relative weights, and the FY 2012 pre-reclassified wage data and applied the estimated readmissions payment adjustment and estimated VBP payment adjustment to aggregate payments using the FY 2012 labor-related share percentages, the proposed FY 2013 relative weights, and the FY 2012 pre-reclassified wage data and applied the same estimated readmissions payment and estimated VBP adjustments. Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.998546. As discussed in section IV. of this Addendum, we also are proposing to apply the DRG reclassification and recalibration budget neutrality factor of 0.998546 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2012.

In order to meet the statutory requirements that we do not take into account the labor-related share of 62 percent when computing wage index budget neutrality, it was necessary to use a three-step process to comply with the requirements that DRG reclassification and recalibration of the relative weights and the updated wage index and labor-related share have no effect on aggregate payments for IPPS hospitals. We first determined a proposed DRG reclassification and recalibration budget neutrality factor of 0.998546 by using the same methodology described above to determine the proposed DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates. Secondly, to compute a proposed budget neutrality factor for wage index and labor-related share changes, we used FY 2011 discharge data to simulate payments and compared aggregate payments using proposed FY 2013 relative weights and FY 2012 pre-reclassified wage indices, applied the FY 2012 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) and applied the estimated readmissions payment adjustment and estimated VBP payment adjustment when estimating aggregate payments using the proposed FY 2013 relative weights and the proposed FY 2013 pre-reclassified wage indices, applied the proposed labor-related share for FY 2013 of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) and applied the same estimated readmissions payment adjustment and estimated VBP payment adjustment. In addition, we applied the proposed DRG reclassification and recalibration budget neutrality factor (derived in the first step) to the rates that were used to simulate payments for this comparison of aggregate payments from FY 2012 to FY 2013. By applying this methodology, we determined a proposed budget neutrality factor of 1.000563 for changes to the wage index. Finally, we multiplied the proposed DRG reclassification and recalibration budget neutrality factor of 0.998546 (derived in the first step) by the proposed budget neutrality factor of 1.000563 for changes to the wage index (derived in the second step) to determine the proposed DRG reclassification and recalibration and updated wage index budget neutrality factor of 0.999108.

b. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with discharges occurring on or after October 1, 1988, certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account ''in applying any budget neutrality adjustment with respect to such index'' under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality factor for FY 2013, we used FY 2011 discharge data to simulate payments and compared total IPPS payments with proposed FY 2013 relative weights, proposed FY 2013 labor-related share percentages, and proposed FY 2013 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act and applied the estimated readmissions payment adjustment and the estimated VBP payment adjustment to total IPPS payments with proposed FY 2013 relative weights, proposed FY 2013 labor-related share percentages, and proposed FY 2013 wage data after such reclassifications and applied the same estimated readmissions payment adjustment and the estimated VBP payment adjustment. Based on these simulations, we calculated a proposed adjustment factor of 0.991436 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2013 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2012 budget neutrality adjustment factor. We note that the proposed FY 2013 budget neutrality adjustment reflects proposed FY 2013 wage index reclassifications approved by the MGCRB or the Administrator.

c. Rural Floor and Imputed Floor Budget Neutrality Adjustment

As noted above, as discussed in section III.G. 2.b. of the preamble of this proposed rule, in the FY 2012 final rule, we extended the imputed floor through FY 2013. We make an adjustment to the wage index to ensure that aggregate payments to hospitals after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) and the imputed floor under § 412.64(h)(4) of the regulations are not affected. In addition, we note in section III.G.2.b. of the preamble of this proposed rule, we are proposing an alternative temporary methodology for computing the imputed floor index. We did not apply this proposed alternative in our calculation of the proposed uniform, national rural floor budget neutrality adjustment to the wage indices because the projected impact of this proposal is less than $5 million and, therefore, would have a negligible impact on the adjustment. If this proposed alternative methodology policy is finalized, we intend to include it in the calculation of the uniform, national rural floor budget neutrality adjustment in the final rule. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

Since FY 2012, there is one hospital in rural Puerto Rico. Therefore, similar to our

calculation in the FY 2012 IPPS/LTCH final rule (76 FR 51593), for FY 2013, we are proposing to calculate a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals in Puerto Rico which receive 75 percent of the national standardized amount) and a rural Puerto Rico-specific wage index (which is used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals in Puerto Rico that receive 25 percent of the Puerto Rico-specific standardized amount). Because this rural Puerto Rico hospital still has no established wage data, our calculation is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). A complete discussion on the computation of the rural Puerto Rico wage index can be found in the FY 2012 final rule.

To calculate the proposed national rural floor and imputed floor budget neutrality factor and Puerto Rico-specific rural floor budget neutrality adjustment factor, we used FY 2011 discharge data and proposed FY 2013 post-reclassified national and Puerto Rico-specific wage indices to simulate IPPS payments. First, we compared the national and Puerto Rico-specific simulated payments without the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to national and Puerto Rico-specific simulated payments with the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to determine the proposed national rural budget neutrality adjustment factor of 0.992243 and the proposed Puerto Rico-specific budget neutrality adjustment factor of 0.990686. The national adjustment was applied to the national wage indices to produce a national rural floor budget neutral wage index and the Puerto Rico-specific adjustment was then applied to the Puerto Rico-specific wage indices to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Proposed Case-Mix Budget Neutrality Adjustment

Below we summarize the proposed adjustments to the FY 2013 rates to account for the effect of changes in documentation and coding that do not reflect real changes in case-mix. We refer the reader to section II.D. of the preamble to this proposed rule for a complete discussion (including our historical adjustments to the rates) on our proposals to eliminate the estimated effect of changes in documentation and coding that do not reflect real changes in case-mix.

(1) Prospective Adjustments for Documentation and Coding in FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes.

For FY 2013, we are proposing a −1.9 percent adjustment to the standardized amount to complete the adjustment required under section 7(b)(1)(A) of Public Law 110–90. We refer the reader to section II.D. of the preamble to this proposed rule for a complete discussion on our historical adjustments and our proposed FY 2013 adjustment to the standardized amount pursuant to section 7(b)(1)(A) of Pub. L. 110–90.

(2) Prospective Adjustments for Documentation and Coding in FY 2010 Authorized by Section 1886(d)(3)(vi) of the Act

Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case mix. After review of comments and recommendations received from MedPAC, we analyzed claims data in FY 2010 to determine whether any additional adjustment would be required to ensure that the introduction of MS–DRGs was implemented in a budget neutral manner. As discussed in section II.D. of the preamble of this proposed rule, our analysis showed a documentation and coding effect in FY 2010 of 0.8 percent, and we are proposing an additional −0.8 percent adjustment to account for the effects of documentation and coding that did not reflect an increase in case-mix severity in FY 2010.

(3) Recoupment or Repayment Adjustment for Documentation and Coding in FY 2008 and FY 2009 Authorized by Section 7(b)(1)(B) of Public Law 110–90

Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data. As discussed in section II.D.5. of the preamble of this proposed rule, we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 would be necessary in order to meet these statutory requirements.

In the FY 2011 IPPS/LTCH PPS final rule, for FY 2011, we made an adjustment to the standardized amount of −2.9 percent, representing approximately half of the required adjustment. For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Pub. L. 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Therefore, the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009 has been completed within the required statutory timeframes. However, to avoid continuing the −2.9 percent adjustment finalized in FY 2012, we are proposing for FY 2013 to make a final +2.9 percent adjustment to the standardized amount. This adjustment removes the onetime −2.9 percent adjustment implemented in FY 2012.

(4) Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

As discussed in section II.D.9. of the preamble of this proposed rule, in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), using the same methodology we applied to estimate documentation and coding changes under IPPS for non-Puerto Rico hospitals, our best estimate, based on the then most recently available data (FY 2009 claims paid through March 2010), was that for documentation and coding changes that occurred over FY 2008 and FY 2009, a cumulative adjustment of −2.6 percent was required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. In FY 2011, as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50071 through 50073), we applied an adjustment of −2.6 percent to the Puerto Rico-specific rate. Therefore, because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, in section II.D.9. of the preamble of this proposed rule, we are proposing to make no further adjustment for FY 2013. For a complete discussion on our proposed policy, we refer readers to section II.D.9. of the preamble of this proposed rule.

We note that, based upon our analysis of FY 2010 claims data; we found no significant additional effect of documentation and coding that would warrant any additional adjustment to the Puerto Rico-specific rate.

e. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.K. of the preamble to this proposed rule, section 410A of Public Law 108–173 originally required the Secretary to establish a demonstration that modifies reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) of Pub. L. 108–173 requires that ''[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.''

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration for an additional 5-year period, and allowed up to 30 hospitals to participate in 20 States with low population densities determined by the Secretary. (In determining which States to include in the expansion, the Secretary is

required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period.) In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51700 through 51705), in order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration as described in section IV.K. of that final rule. In other words, we applied budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration, consistent with past practice. We stated that we believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that ''aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented,'' but does not identify the range across which aggregate payments must be held equal.

For FY 2013, for the 23 hospitals participating in the demonstration project, we are proposing to adjust the national IPPS rates according to the methodology set forth elsewhere in this proposed rule. For this proposed rule, the estimated amount for the adjustment to the national IPPS rates for FY 2013 is $35,077,708. Accordingly, to account for the estimated costs of the demonstration for the specific time periods as explained in detail in section IV.K. of the preamble of this proposed rule, for FY 2013, we computed a proposed factor of 0.999629 for the rural community hospital demonstration program budget neutrality adjustment that would be applied to the IPPS standardized rate.

We note that if updated data become available prior to the FY 2013 final rule, we are proposing to use them, to the extent appropriate, to estimate the costs of the demonstration program in FY 2013. Therefore, this estimated budget neutrality offset amount may change in the final rule depending on the availability of updated data. In addition, if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009, or 2010) are available prior to the FY 2013 IPPS/LTCH PPS final rule, we are proposing to incorporate into the FY 2013 budget neutrality offset amount the difference between the final cost of the demonstration in any of these years (as described previously) and the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule.

f. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2013 is 80 percent, the same marginal cost factor we have used since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments. We note that the statute requires outlier payments to be not less than 5 percent nor more than 6 percent of total ''operating DRG payments'' (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary to reduce the average standardized amount applicable to hospitals located in Puerto Rico to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/04_outlier.asp#TopOfPage.*

(1) Proposed FY 2013 Outlier Fixed-Loss Cost Threshold

For FY 2013, we are proposing to continue to use the same methodology used for FY 2009 (73 FR 48763 through 48766) to calculate the outlier threshold. Similar to the methodology used in the FY 2009 IPPS final rule, for FY 2013, we are proposing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). As we have done in the past, to calculate the proposed FY 2013 outlier threshold, we simulated payments by applying proposed FY 2013 rates and policies using cases from the FY 2011 MedPAR files. Therefore, in order to determine the proposed FY 2013 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2011 to FY 2013.

We are proposing to continue to use a refined methodology that takes into account the lower inflation in hospital charges that are occurring as a result of the outlier final rule (68 FR 34494), which changed our methodology for determining outlier payments by implementing the use of more current CCRs. Our refined methodology uses more recent data that reflect the rate-of-change in hospital charges under the new outlier policy.

Using the most recent data available, we calculated the 1-year average annualized rate-of-change in charges per case from the last quarter of FY 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010) to the last quarter of FY 2011 in combination with the first quarter of FY 2012 (July 1, 2011 through December 31, 2011). This rate-of-change was 6.8 percent (1.068003) or 14.06 percent (1.140630) over 2 years. As we have done in the past, we established the proposed FY 2013 outlier threshold using hospital CCRs from the December 2011 update to the Provider-Specific File (PSF)—the most recent available data at the time of this proposed rule.

As discussed in the FY 2007 IPPS final rule (71 FR 48150), we worked with the Office of Actuary to derive the methodology described below to develop the CCR adjustment factor. For FY 2013, we are proposing to continue to use the same methodology to calculate the CCR adjustment by using the FY 2011 operating cost per discharge increase in combination with the actual FY 2011 operating market basket percentage increase determined by IHS Global Insight, Inc. (IGI), as well as the charge inflation factor described above to estimate the adjustment to the CCRs. (We note that the FY 2011 actual (otherwise referred to as ''final'') operating market basket percentage increase reflects historical data, whereas the published FY 2011 operating market basket update factor was based on IGI's 2010 second quarter forecast with historical data through the first quarter of 2010. We also note that while the FY 2011 published operating market basket update was based on the FY 2002-based IPPS market basket, the actual or ''final'' market basket percentage increase is based on the FY 2006-based IPPS market basket. Similarly, the FY 2011 published capital market basket update factor was based on the FY 2002-based capital market basket and the actual or ''final'' capital market basket percentage increase is based on the FY 2006-based capital market basket.) By using the operating market basket percentage increase and the increase in the average cost per discharge from hospital cost reports, we are using two different measures of cost inflation. For FY 2013, we determined the adjustment by taking the percentage increase in the operating costs per discharge from FY 2009 to FY 2010 (1.0160) from the cost report and dividing it by the final operating market basket percentage increase from FY 2010 (1.0210). This operation removes the measure of pure price increase (the market basket) from the percentage increase in operating cost per discharge, leaving the nonprice factors in the cost increase (for example, quantity and changes in the mix of goods and services). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the operating market basket percentage increase and the increase in cost per case from the cost report (the FY 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0505 divided by the FY 2008 final operating market basket percentage

increase of 1.0400, the FY 2008 to FY 2009 percentage increase of operating costs per discharge of 1.0295 divided by the FY 2009 final operating market basket percentage increase of 1.0260). For FY 2013, we averaged the differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0029. We multiplied the 3-year average of 1.0029 by the FY 2011 final operating market basket percentage increase of 1.0270, which resulted in an operating cost inflation factor of 2.99 percent or 1.029948. We then divided the operating cost inflation factor by the 1-year average change in charges (1.068003) and applied an adjustment factor of 0.964368 to the operating CCRs from the PSF (calculation performed on unrounded numbers).

As stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a fiscal intermediary or MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average ''age'' of hospitals' CCRs from the time the fiscal intermediary or the MAC inserts the CCR in the PSF until the beginning of FY 2009 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

We used the same methodology for the capital CCRs and determined the adjustment by taking the percentage increase in the capital costs per discharge from FY 2009 to FY 2010 (1.0102) from the cost report and dividing it by the final capital market basket percentage increase from FY 2010 (1.010). We repeated this calculation for 2 prior years to determine the 3-year average of the rate of adjusted change in costs between the capital market basket percentage increase and the increase in cost per case from the cost report (the FY 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0809 divided by the FY 2008 final capital market basket percentage increase of 1.0150, the FY 2008 to FY 2009 percentage increase of capital costs per discharge of 1.0499 divided by the FY 2009 final capital market basket percentage increase of 1.0150). For FY 2013, we averaged the differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0332. We multiplied the 3-year average of 1.0332 by the FY 2011 final capital market basket percentage increase of 1.0120, which resulted in a capital cost inflation factor of 4.56 percent or 1.045567. We then divided the capital cost inflation factor by the 1-year average change in charges (1.068003) and applied an adjustment factor of 0.978993 to the capital CCRs from the PSF (calculation performed on unrounded numbers). We are proposing to use the same charge inflation factor for the capital CCRs that was used for the operating CCRs. The charge inflation factor is based on the overall billed charges. Therefore, we believe it is appropriate to apply the charge factor to both the operating and capital CCRs.

As stated above, for FY 2013, we applied the proposed FY 2013 rates and policies using cases from the FY 2011 MedPAR files in calculating the proposed outlier threshold.

As discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.G.3. of the preamble of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, beginning in FY 2011, we created a wage index floor of 1.00 for all hospitals located in States determined to be frontier States. We noted that the frontier State floor adjustments will be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index lesser than 1.00 due to the rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2013, it was necessary to apply this provision by adjusting the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2013. If we did not take into account this provision, our estimate of total FY 2013 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

Our estimate of the cumulative effect of changes in documentation and coding due to the adoption of the MS–DRGs of 5.4 percent from FY 2008 and FY 2009 and 0.8 percent from FY 2010 is already included within the claims data (FY 2011 MedPAR files) used to calculate the proposed FY 2013 outlier threshold. We currently estimate that there would be no continued changes in documentation and coding in FYs 2011 and 2012. Therefore, the cumulative effect of documentation and coding that has occurred is already reflected within the FY 2011 MedPAR claims data, and we do not believe there is any need to inflate FY 2011 claims data for any additional case-mix growth projected to have occurred since FY 2010.

In addition, we are not proposing to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also note that reconciliation occurs because hospitals' actual CCRs for the cost reporting period are different than the interim CCRs used to calculate outlier payments when a bill is processed. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions about the effects of reconciliation on the outlier threshold calculation.

As described in sections IV.A. and VIII.B., respectively, of the preamble of this proposed rule, section 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program. We do not believe it is appropriate to include the hospital VBP payment adjustment and the readmissions payment adjustment in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our proposed definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under proposed § 412.152 and the Hospital VBP Program (that is, the wage-adjusted DRG operating payment amount) under proposed § 412.160, outlier payments under section 1886(d)(5)(F) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the operating base DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP adjustment). Consequently, we are proposing to exclude the hospital VBP payment adjustment and the readmissions payment adjustment from the calculation of the outlier fixed-loss cost threshold.

Using this methodology, we are proposing an outlier fixed-loss cost threshold for FY 2013 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $27,425.

We note that the proposed FY 2013 outlier fixed-loss cost threshold represents a $5,040 (or 22.5 percent) increase from the final FY 2012 final outlier fixed-loss cost threshold of $22,385. Since FY 2009, the outlier fixed-loss cost threshold has been between $20,185 and $23,140. Therefore, we are concerned about this large increase in the outlier fixed-loss cost threshold from FY 2012.

We further note that the 2-year charge inflation factor of 14.06 percent applied to the FY 2011 MedPAR claims used to compute the FY 2013 outlier fixed-loss cost threshold is higher than the 2-year charge inflation factor of 7.94 percent applied to the FY 2010 MedPAR claims used to compute the FY 2012 final outlier fixed-loss cost threshold. We believe that a large increase in the charge inflation factor for FY 2013 (from FY 2012) increased projected total outlier payments. With an increase in projected outlier payments, in order for CMS to meet the 5.1 percent target, it would be necessary to reduce the amount of outlier payments by raising the outlier fixed-loss cost threshold. Therefore, in addition to being concerned about the large increase in the fixed-loss threshold proposed for FY 2013 compared to FY 2012, we are concerned about this large charge inflation increase and how it potentially affected the proposed FY 2013 outlier fixed-loss cost threshold. As described above, to determine the 1-year average annualized rate-of-change in charges per case, we currently use a methodology that compares the average charge per case from the most recent 6-month period of

MedPAR data that are available to the same 6-month period of MedPAR data from the prior year. We adopted this methodology in the FY 2005 IPPS final rule (69 FR 49277) as a result of the special circumstances surrounding the revisions to the outlier payment methodology at that time. In that rule, we stated that we would continue to consider other methodologies for determining charge inflation when calculating the outlier threshold in the future. We welcomed comment on possible modifications to our current methodologies, including the possibility of looking at a larger time period beyond 6 months to determine the average charge per case to measure the charge inflation factor.

In addition, as pointed out by commenters in last year's final rule (76 FR 51793 through 51795), CMS has not met the 5.1 percent target for some time and the commenters have recommended enhancements to the methodology to improve the calculation of the outlier fixed-loss cost threshold. Commenters have focused on CMS underestimating actual outlier payments. Since FY 2009, we have used the same methodology to calculate the outlier fixed-loss cost threshold. While we have been reluctant to make changes to our methodology, as discussed below, our estimate for FY 2011 is that outlier payments will be approximately 4.7 percent of actual total DRG payments and for FY 2012 outlier payments will be approximately 6.0 percent of actual total DRG payments. While these estimates differ—with one being under the target and one above the target—they draw attention to the potential for improving our estimation methodology so that we meet the 5.1 percent target. We welcome public comment on ways to enhance the accuracy of our methodology of the calculation of the FY 2013 outlier fixed-loss cost threshold, especially additional analyses that could inform potential technical improvements.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2013 would result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.99 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2013 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2013 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948992	0.940035
Puerto Rico	0.953161	0.923900

We are proposing to apply the outlier adjustment factors to the proposed FY 2013 rates after removing the effects of the FY 2012 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the fiscal intermediary or MAC computes operating CCRs greater than 1.137 or capital CCRs greater than 0.158, or hospitals for which the fiscal intermediary or MAC is unable to calculate a CCR (as described at § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the fiscal intermediary or MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2012, these statewide average ratios would replace the ratios posted on the Internet at *http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp#TopOfPage*. Table 8B listed in section VI. of this Addendum (and available via the Internet) contains the proposed comparable statewide average capital CCRs. Again, the CCRs in Tables 8A and 8B would be used during FY 2013 when hospital-specific CCRs based on the latest settled cost report are either not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their fiscal intermediary or MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the fiscal intermediary or MAC can avoid possible overpayments or underpayments at cost report settlement, thus ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. Additionally, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010 which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2011 and FY 2012 Outlier Payments

In the FY 2012 IPPS final rule (76 FR 51795 through 51796), we stated that, based on available data, we estimated that actual FY 2011 outlier payments would be approximately 4.7 percent of actual total DRG payments. This estimate was computed based on simulations using the FY 2010 MedPAR file (discharge data for FY 2010 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2011 claims, but instead reflected the application of FY 2011 rates and policies to available FY 2010 claims.

Our current estimate, using available FY 2011 claims data, is that actual outlier payments for FY 2011 were approximately 4.7 percent of actual total DRG payments. Thus, the data indicate that, for FY 2011, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 20110. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not plan to make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2011 are equal to 5.1 percent of total DRG payments.

We currently estimate that actual outlier payments for FY 2012 will be approximately 6.0 percent of actual total DRG payments, approximately 0.9 percentage points higher than the 5.1 percent we projected when setting the outlier policies for FY 2012. This estimate of 6.0 percent is based on simulations using the FY 2011 MedPAR file (discharge data for FY 2011 claims).

5. Proposed FY 2013 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet) contain the proposed national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2013. The proposed Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is the labor-related share of 68.8 percent, and Table

1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals (other than those in Puerto Rico) whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the applicable percentage increase of 2.1 percent for FY 2013, and a proposed update of 0.1 percent for hospitals that fail to submit quality data consistent with section 1886(b)(3)(B)(viii) of the Act.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount (this amount is set forth in Table 1A). The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2013 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). This table also includes the proposed Puerto Rico standardized amounts. The labor-related share applied to the Puerto Rico specific standardized amount is the labor-related share of 62.1 percent, or 62 percent, depending on which provides higher payments to the hospital.(Section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.)

The following table illustrates the proposed changes from the FY 2012 national standardized amount. The second column shows the proposed changes from the FY 2012 standardized amounts for hospitals that satisfy the quality data submission requirement and therefore receive the full proposed update of 2.1 percent. The third column shows the proposed changes for hospitals receiving the proposed reduced update of 0.1 percent. The first row of the table shows the updated (through FY 2012) average standardized amount after restoring the FY 2012 offsets for outlier payments, demonstration budget neutrality, the geographic reclassification budget neutrality and the retrospective documentation and coding adjustment under section 7(b)(1)(B) of Public Law 110–90. The DRG reclassification and recalibration wage index budget neutrality factors are cumulative. Therefore, those FY 2012 factors are not removed from this table.

COMPARISON OF FY 2012 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2013 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE

	Full update (2.1 percent); wage index is greater than 1.0000	Full update (2.1 percent); wage index is less than or equal to 1.0000	Reduced update (0.1 percent); wage index is greater than 1.0000	Reduced update (0.1 percent); wage index is less than or equal to 1.0000
FY 2012 Base Rate, after removing geographic reclassification budget neutrality, demonstration budget neutrality, cumulative FY 2008 and FY 2009 documentation and coding adjustment, FY 2012 documentation and coding recoupment, and outlier offset (based on the labor-related share percentage for FY 2012).	Labor: $4,060.65 ..... Nonlabor: $1,841.46 ..	Labor: $3,659.31 ..... Nonlabor: $2,242.80 ..	Labor: $4,060.65 ..... Nonlabor: $1,841.46 ..	Labor: $3,659.31. Nonlabor: $2,242.80.
Proposed FY 2013 Update Factor	1.021	1.021	0.001	0.001.
Proposed FY 2013 DRG Recalibration and Wage Index Budget Neutrality Factor.	0.999108	0.999108	0.999108	0.999108.
Proposed FY 2013 Reclassification Budget Neutrality Factor.	0.991436	0.991436	0.991436	0.991436.
Proposed FY 2013 Rural Demonstration Budget Neutrality Factor.	0.999629	0.999629	0.999629	0.999629.
Proposed FY 2013 Outlier Factor	0.948992	0.948992	0.948992	0.948992.
Documentation and coding adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90.	0.9405	0.9405	0.9405	0.9405.
Proposed Rate for FY 2013	Labor: $3,664.03 ..... Nonlabor: $1,661.59 ..	Labor: $3,301.88 ..... Nonlabor: $2,023.74 ..	Labor: $3,592.26 ..... Nonlabor: $1,629.04 ..	Labor: $3,237.21. Nonlabor: $1,984.09.

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet), contain the proposed labor-related and nonlabor-related shares that we used to calculate the proposed prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2013. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national and Puerto Rico prospective payment rates, respectively, to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the proposed FY 2013 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make ''such adjustments * * * as the Secretary deems appropriate'' to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp* to update this nonlabor portion.

Sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Public Law 111–84, locality pay is being phased in

over a 3-year period beginning in January 2010 with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay. As we discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51797), we did not believe it was appropriate to use the 2010 or 2011 reduced factors for adjusting the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii.

We believe it was appropriate to use ''frozen'' COLA factors to adjust payments in FY 2012 while we explored alternatives for updating the COLA adjustment in the future. In this proposed rule, for FY 2013, we are now proposing to continue to use the same ''frozen'' COLA factors used in FY 2012 and to update the COLA factors for Alaska and Hawaii beginning in FY 2014 based on a comparison of the growth in the Consumer Price Indices (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). Specifically, for FY 2014, we would update the COLA factors published by OPM that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay. Because BLS publishes CPI data for only Anchorage and Honolulu, we are proposing to use the comparison of the growth in the overall CPI relative to the growth in the CPI for those cities to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the U.S. (as measured by the CPIs mentioned above) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the U.S.

BLS publishes the CPI for All Items for Anchorage, Honolulu, and for the average U.S. city. However, we are proposing to create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is compromised of approximately 60 percent commodities and 40 percent services. Therefore, we are proposing to create reweighted indexes for Anchorage, Honolulu, and the average U.S. city using the respective CPI commodities index and CPI services index using the 60/40 share obtained from the IPPS market basket. We believe this proposed methodology is appropriate because we would continue to make a COLA adjustment for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent, and since at least 1984, we have exercised our discretionary authority to adjust Alaska and Hawaii payments by incorporating this cap. In keeping with this historical policy, our proposal for FY 2014 would continue to use such a cap, as our proposal is based on OPM's COLA factors (updated by the proposed methodology described above).

Lastly, we are proposing to update the COLA factors based on our proposed methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket. The labor-related share of the IPPS market basket is currently not scheduled to be updated until FY 2014. Accordingly, under this proposal, we would begin applying this proposed methodology to update the COLA factors to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii for FY 2014. At the time of development of the FY 2014 proposed rule, we expect to have CPI data available through 2012. Therefore, the proposed FY 2014 COLA factors for Alaska and Hawaii would be based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the reweighted CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the reweighted CPI for the average U.S. city.

However, in this proposed rule, for FY 2013, we are proposing to use the same COLA factors used to adjust payments in FY 2012 (as originally used to adjust payments in FY 2011, which are based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The table below shows the COLA factors that we are proposing to use for FY 2013:

TABLE OF PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2012

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs, for FY 2013 equals the Federal rate. (As noted above, due to the expiration of the MDH program, beginning with FY 2013, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2013.)

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2013 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for hospitals located in Puerto Rico for FY 2013 equals 25 percent of the Puerto Rico rate plus 75 percent of the applicable national rate.

1. Federal Rate

The Federal rate is determined as follows:

Step 1—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data (full update for hospitals submitting quality data; update including a −2.0 percent adjustment for hospitals that did not submit these data).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—For hospitals in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the applicable cost-of-living adjustment factor.

Step 4—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3).

Step 5—Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS–DRG (Table 5 listed in section VI. of this Addendum and available via the Internet).

The Federal rate as determined in Step 5 may then be further adjusted if the hospital qualifies for either the IME or DSH adjustment. In addition, for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b), the payment in Step 5 would be increased by the formula described in section IV.D. of the preamble of this proposed rule. Finally, the base operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP adjustment as described under sections 1886 (q) and 1886(o) of the Act.

2. Hospital-Specific Rate (Applicable Only to SCHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that currently SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on the FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. For a more detailed discussion of the calculation of the hospital-specific rates, we refer the reader to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

We note that, in the FY 2012 IPPS/LTCH final rule (76 FR 51799), we finalized an adjustment of 0.9 percent to the hospital-specific rate (that is, a factor of 1.009) to remove the effects of the rural floor from the hospital-specific rates for FYs 1998 through 2005. The adjustment is a onetime permanent adjustment to the hospital-specific rates.

b. Updating the FY 1982, FY 1987, FY 1996 and FY 2006 Hospital-Specific Rate for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs equal to the update factor for all other IPPS hospitals, the update to the hospital specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increase to the hospital-specific rates applicable to SCHs is 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for multifactor productivity and less 0.1 percentage point) for hospitals that submit quality data or 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.8 percentage point for multifactor productivity, and less 0.1 percentage point) for hospitals that fail to submit quality data. For a complete discussion of the applicable percentage increase applicable to the hospital-specific rates for SCHs, we refer readers to section IV.B. of the preamble of this proposed rule.

In addition, because SCHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the DRG classifications and the recalibration of the DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, a SCH's hospital-specific rate is adjusted by the proposed DRG reclassification and recalibration budget neutrality factor of 0.998546, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate an SCH would receive for its discharges beginning on or after October 1, 2012.

c. Documentation and Coding Adjustment to the FY 2013 Hospital-Specific Rate for SCHs

As discussed in section II.D. of the preamble of this proposed rule, because hospitals paid based in whole or in part on the hospital-specific rate (that is, SCHs and former MDHs) use the same MS–DRG system as other hospitals, we believe they have the potential to realize increased payments from documentation and coding changes that do not reflect real increases in patients' severity of illness. Under section 1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rate should not have the potential to realize increased payments due to documentation and coding changes that do not reflect real increases in patients' severity of illness. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50426) and in section II.D. of the preamble of this proposed rule, we believe they should be equally subject to a prospective budget neutrality adjustment that we are applying for adoption of the MS–DRGs to all other hospitals. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act.

As we discuss in section II.D. of the preamble of this proposed rule, we have determined that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of changes in documentation and coding that occurred in FY 2008 and FY 2009 on future payments to SCHs. Currently, we have made cumulative adjustments to the hospital-specific rates to account for 4.9 percent of the 5.4 percent effect of changes in documentation and coding that occurred in FY 2008 and FY 2009. (For FY 2011, we established a prospective adjustment of −2.9 percent to the hospital-specific rates, and, for FY 2012, we established a prospective adjustment to the hospital-specific rates of −2.0 percent.) In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51499), we indicated that, because the −2.0 percent adjustment we made in FY 2012 did not reflect the entire remaining requirement adjustment amount of −2.5 percent, an additional −0.5 percent adjustment to the hospital-specific rates would be required in future rulemaking.

In this proposed rule, we are proposing a −0.5 percent prospective adjustment to the hospital-specific rate to account for the remainder of the 5.4 percent effect of documentation and coding that occurred in FY 2008 and FY 2009. We continue to believe that hospitals paid based on their hospital-specific rate (that is, SCHs) had the same opportunity to benefit for improvements in documentation and coding that did not reflect an increase in patient severity, and we continue to believe that any resulting adjustments should be applied similarly to all subsection (d) hospitals, when possible.

As discussed in section II.D., after review of comments and recommendations received from MedPAC, we analyzed claims data in FY 2010 to determine whether any additional adjustment (beyond the estimated 5.4 percent for FYs 2008 and 2009 discussed above) to the hospital-specific rate would be required to ensure that the introduction of MS–DRGs was implemented in a budget neutral manner. We analyzed FY 2010 claims data (for this proposed rule, we analyzed FY 2010 claims paid through December 2011), and determined that there is an additional documentation and coding effect of 0.8 percent.

Consistent with our proposal for IPPS hospitals based upon a review of FY 2010 claims data using the same methodology, we also are proposing an additional −0.8 percent adjustment to the hospital-specific rates to account for documentation and coding that did not reflect an actual increase in case-mix in FY 2010. We believe that a full prospective adjustment is the most appropriate means to take into account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between different IPPS hospitals paid using the MS–DRG. Therefore, as discussed in more detail the preamble to this proposed rule, we are proposing a combined adjustment of −1.3 percent (−0.5 percent + −0.8 percent) to the hospital-specific rates, accounting for all documentation and coding effects observed between FY 2008 though FY 2010.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or After October 1, 2012, and Before October 1, 2013

Section 1886(d)(9)(E)(iv) of the Act provides that, effective for discharges occurring on or after October 1, 2004, hospitals located in Puerto Rico are paid based on a blend of 75 percent of the national prospective payment rate and 25 percent of the Puerto Rico-specific rate.

a. Puerto Rico Rate

The Puerto Rico prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount considering the applicable wage index (Table 1C published in section VI. of this Addendum and available via the Internet).

Step 2—Multiply the labor-related portion of the standardized amount by the applicable Puerto Rico-specific wage index.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (Table 5 listed in section VI. of this Addendum and available via the Internet).

Step 5—Multiply the result in Step 4 by 25 percent.

b. National Rate

The national prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount.

Step 2—Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3—Add the amount from Step 2 and the nonlabor-related portion of the national average standardized amount.

Step 4—Multiply the amount from Step 3 by the applicable MS–DRG relative weight (Table 5 listed in section VI. of this Addendum and available via the Internet).

Step 5—Multiply the result in Step 4 by 75 percent.

The sum of the Puerto Rico rate and the national rate computed above equals the prospective payment for a given discharge for a hospital located in Puerto Rico. This rate is then further adjusted if the hospital qualifies for either the IME or DSH adjustment.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2013

The PPS for acute-care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, hospitals were paid during a 10-year transition period (which extended through FY 2001) to change the payment methodology for Medicare acute care hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. Below we discuss the factors that we used to determine the proposed capital Federal rate for FY 2013, which will be effective for discharges occurring on or after October 1, 2012.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in below in section III.A.4. of this Addendum, there is no longer a need for an exceptions payment adjustment factor.) Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. In accordance with section 1886(d)(9)(A) of the Act, under the IPPS for acute care hospital operating costs, hospitals located in Puerto Rico are paid for operating costs under a special payment formula. Effective October 1, 2004, in accordance with section 504 of Pub. L. 108–173, the methodology for operating payments made to hospitals located in Puerto Rico under the IPPS was revised to make payments based on a blend of 25 percent of the applicable standardized amount specific to Puerto Rico hospitals and 75 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges occurring on or after October 1, 2004, we also revised the methodology for computing capital payments to hospitals located in Puerto Rico to be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the national capital Federal rate (69 FR 49185).

A. Determination of Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the proposed capital Federal rate for FY 2013. In particular, we explain why the proposed FY 2013 capital Federal rate increases approximately 0.7 percent, compared to the FY 2012 capital Federal rate. As discussed in the impact analysis in Appendix A of this proposed rule, we estimate that capital payments per discharge will decrease 0.2 percent during that same period. Because capital payments constitute about 10 percent of hospital payments, a percent change in the capital Federal rate yields only about a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2013 under that framework is 1.3 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.3 percent increase in the CIPI, a 0.0 percent adjustment for intensity, a 0.0 percent adjustment for case-mix, a 0.0 percent adjustment for the FY 2011 DRG reclassification and recalibration, and a forecast error correction of 0.0 percent. As discussed below in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2013 CIPI projection in that same section of this Addendum. We note that, as discussed in section V.C. of the preamble of this proposed rule, we are proposing to apply a −0.8 percent adjustment to the capital rate in FY 2013 to account for the effect of changes in documentation and coding under the MS–DRGs that do not correspond to changes in real increases in patients' severity of illness. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2013.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patients changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher weight DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher weighted DRGs but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B in the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2013, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will also equal 0.5 percent for FY 2013. The proposed net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, the proposed net adjustment for case-mix change in FY 2013 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2011 DRG reclassification and recalibration as part of our update for FY 2013. We estimate that FY 2011 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percent adjustment for reclassification and recalibration in the update framework for FY 2013.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. A forecast error of 0.0 percentage point was calculated for the proposed FY 2013 update. That is, current historical data indicate that the forecasted FY 2011 CIPI (1.2 percent) used in calculating the FY 2011 update factor is the same as the actual realized price increases (1.2 percent). Because we estimate forecast error for the FY 2011 CIPI, we are proposing to make a 0.0 percent adjustment for forecast error in the update for FY 2013.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove non-cost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CIPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2013 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2013, we are proposing to use an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2005 and extending through FY 2010. Based on these data, we estimated that case-mix constant intensity declined during FYs 2005 through 2010. In the past, when we found intensity to be declining, we believed a zero (rather than negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2013. Therefore, we are proposing to make a 0.0 percent adjustment for intensity in the update for FY 2013.

Above, we described the basis of the components used to develop the proposed 1.3 percent capital update factor under the capital update framework for FY 2013 as shown in the table below.

PROPOSED CMS FY 2013 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index	1.3
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	−0.5
Projected Case-Mix Change	0.5
Subtotal	1.3
Effect of FY 2011 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.3

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2012 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2013. (MedPAC's Report to the Congress: Medicare Payment Policy, March 2012, Chapter 3.)

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2012, we estimated that outlier payments for capital would equal 6.18 percent of inpatient capital-related payments based on the capital Federal rate in FY 2012. Based on the thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 6.00 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2013. Therefore, we are proposing to apply an outlier adjustment factor of 0.9400 in determining the capital Federal rate for FY 2013. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2013 will be somewhat lower than the percentage for FY 2012. This decrease in estimated capital outlier payments is primarily due to the proposed increase in the outlier threshold used to identify outlier cases for both inpatient operating and inpatient capital-related payments, which is discussed in section II.A. of this Addendum. That is, because the outlier threshold used to identify outlier cases is higher, cases will receive lower outlier payments and fewer cases will qualify for outlier payments.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2013 outlier adjustment of 0.9400 is a 0.19 percent change from the FY 2012 outlier adjustment of 0.9382. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2013 is 1.0019 (0.9400/0.9382). Thus, the proposed outlier adjustment will increase the FY 2013 capital Federal rate by 0.19 percent compared with the FY 2012 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we implemented a separate GAF for Puerto Rico, we apply separate budget neutrality adjustments for the national GAF and the Puerto Rico GAF. We apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. Separate adjustments were unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was implemented in FY 1998.

To determine the proposed factors for FY 2013, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2012 MS–DRG classifications and relative weights and the FY 2012 GAF to estimated aggregate capital Federal rate payments based on the FY 2012 MS–DRG classifications and relative weights and the proposed FY 2013 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment of 1.0006 for FY 2013 to the previous cumulative FY 2012 adjustment of 0.9905, yielding an adjustment of 0.9911, through FY 2013. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment of 1.0044 for FY 2013 to the previous cumulative FY 2012 adjustment of 1.0043, yielding a cumulative adjustment of 1.0087 through FY 2013.

We then compared estimated aggregate capital Federal rate payments based on the FY 2012 DRG relative weights and the proposed FY 2013 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2013 MS–DRG classifications and relative weights and the proposed FY 2013 GAFs. The proposed incremental adjustment for DRG classifications and proposed changes in relative weights is 0.9996 both nationally and for Puerto Rico. The proposed cumulative adjustments for MS–DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2012 are 0.9907 nationally and 1.0083 for Puerto Rico. We note that all the values are calculated with unrounded numbers.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor (the national capital rate and the Puerto Rico capital rate are determined separately) for changes in the GAF (including geographic reclassification) and the DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

For FY 2012, we established a GAF/DRG budget neutrality factor of 1.0004 (76 FR 51803). For FY 2013, we are proposing to establish a GAF/DRG budget neutrality factor of 1.0002. The GAF/DRG budget neutrality factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs. The incremental change in the adjustment from FY 2012 to FY 2013 is 1.0002. The proposed cumulative change in the capital Federal rate due to this adjustment is 0.9907 (the product of the incremental factors for FYs 1995 through 2012 and the proposed incremental factor of 1.0002 for FY 2013). (For a listing of the DRG and GAF budget neutrality adjustment factors, we refer readers to section V. of the Addendum to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51803).)

The proposed factor accounts for the proposed MS–DRG reclassifications and recalibration and for proposed changes in the GAFs. It also incorporates the effects on the proposed GAFs of FY 2013 geographic reclassification decisions made by the MGCRB compared to FY 2012 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) of our regulations requires that the capital standard Federal rate be reduced by an adjustment factor equal to the estimated proportion of additional payments for both regular exceptions and special exceptions under § 412.348 relative to total capital PPS payments.

Since FY 2002, an adjustment for regular exception payments was no longer necessary in determining the capital Federal rate because, in accordance with § 412.348(b), regular exception payments were only made for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001. Accordingly, in FY 2002 and subsequent fiscal years, no payments are made under the regular exceptions provision (66 FR 39949). Furthermore, as discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51804), there are no longer any remaining hospitals eligible to receive a special exceptions payment under § 412.348(g) because they have reached the limitation on the period for exception payments under § 412.348(g)(7). Therefore, beginning with FY 2012, there is no longer a need for an exceptions payment adjustment factor.

5. Proposed Capital Standard Federal Rate for FY 2013

For FY 2012, we established a capital Federal rate of $421.42 (76 FR 51804). We are proposing to establish an update of 1.3 percent in determining the FY 2013 capital Federal rate for all hospitals. However, as discussed in greater detail in section V.E. of the preamble of this proposed rule, under the statutory authority at section 1886(g) of the Act, consistent with section 1886(d)(3)(A)(vi) of the Act and section 7(b) of Pub. L. 110–90, we are proposing to make an additional 0.8 percent reduction to the national capital Federal payment rate in FY 2013 to account for the effect of changes in case-mix resulting from documentation and coding changes that do not reflect real changes in the case-mix in light of the adoption of MS–DRGs. Accordingly, we are proposing to apply a cumulative documentation and coding adjustment factor of 0.9404 in determining the proposed FY 2013 capital Federal rate (that is, the existing −0.6 percent adjustment in FY 2008 plus the −0.9 percent adjustment in FY 2009, plus the −2.9 percent adjustment for FY 2011, plus the −1.0 percent adjustment for FY 2012, plus the proposed −0.8 percent adjustment for FY 2013, computed as 1 divided by $(1.006 \times 1.009 \times 1.029 \times 1.010 \times 1.008)$. (We note that we did not apply a documentation and coding adjustment to the capital Federal rate in FY 2010 (74 FR 43927).) As a result of the proposed 1.3 percent update and other budget neutrality factors discussed above, we are proposing to establish a national capital Federal rate of $424.42 for FY 2013. The proposed national capital Federal rate for FY 2013 was calculated as follows:

- The proposed FY 2013 update factor is 1.0130, that is, the proposed update is 1.3 percent.
- The proposed FY 2013 budget neutrality adjustment factor that is applied to the proposed capital standard Federal payment rate for proposed changes in the MS–DRG classifications and relative weights and proposed changes in the GAFs is 1.0002.
- The proposed FY 2013 outlier adjustment factor is 0.9400.
- The proposed cumulative adjustment factor for FY 2013 applied to the national capital Federal rate for changes in documentation and coding under the MS–DRGs is 0.9404.

Because the proposed capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not proposing to make additional adjustments in the capital standard Federal rate for these factors, other than the proposed budget neutrality factor for proposed changes in the MS–DRG classifications and relative weights and for proposed changes in the GAFs. (As discussed in section III.A.4. of this Addendum, there is no longer a need for an exceptions payment adjustment factor in determining the capital Federal rate.)

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2013 affects the computation of the proposed FY 2013 national capital Federal rate in comparison to the FY 2012 national capital Federal rate. The proposed FY 2013 update factor has the effect of increasing the capital Federal rate by 1.3 percent compared to the FY 2012 capital Federal rate. The proposed GAF/DRG budget neutrality factor has the effect of increasing the capital Federal rate by 0.02 percent. The proposed FY 2013 outlier adjustment factor has the effect of increasing the proposed capital Federal rate by 0.19 percent compared to the FY 2012 capital Federal rate. The proposed factor for changes in documentation and coding under the MS–DRGs for FY 2013 has the net effect of decreasing the proposed FY 2013 national capital Federal rate by 0.08 percent as compared to the FY 2012 national capital Federal rate. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by approximately 0.7 percent compared to the FY 2012 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2012 CAPITAL FEDERAL RATE AND PROPOSED FY 2013 CAPITAL FEDERAL RATE

	FY 2012	Proposed FY 2013	Change	Percent change
Update Factor [1]	1.0150	1.0130	1.0130	1.30
GAF/DRG Adjustment Factor [1]	1.004	1.0002	1.0002	0.02
Outlier Adjustment Factor [2]	0.9382	0.9400	1.0019	0.19
MS–DRG Documentation and Coding Adjustment Factor	[3] 0.9479	[4] 0.9404	0.9921	−0.79
Capital Federal Rate [5]	$421.42	$424.42	1.0071	0.71

[1] The update factor and the GAF/DRG budget neutrality factors are built permanently into the capital rates. Thus, for example, the incremental change from FY 2012 to FY 2013 resulting from the application of the proposed 1.0002 GAF/DRG budget neutrality factor for FY 2013 is a net change of 1.0002.

[2] The outlier reduction factor is not built permanently into the capital rate; that is, the factor is not applied cumulatively in determining the capital rate. Thus, for example, the net change resulting from the application of the FY 2013 outlier adjustment factor is 0.9404/0.9382, or 1.0019.

[3] The documentation and coding adjustment factor includes the −0.6 percent in FY 2008, −0.9 percent in FY 2009, no additional reduction in FY 2010, the −2.9 percent in FY 2011 and the −1.0 percent in FY 2012.

[4] The documentation and coding adjustment factor includes the −0.6 percent in FY 2008, −0.9 percent in FY 2009, no additional reduction in FY 2010, the −2.9 percent in FY 2011, the −1.0 percent in FY 2012, and the proposed −0.8 percent in FY 2013.

[5] Sum of percent change may not sum due to rounding.

6. Proposed Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments to hospitals located in Puerto Rico under the PPS for acute care hospital inpatient capital-related costs. Accordingly, under the capital PPS, we compute a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Under the broad authority of section 1886(g) of the Act, beginning with discharges occurring on or after October 1, 2004, capital payments to hospitals located in Puerto Rico are based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate. The Puerto Rico capital rate is derived from the costs of Puerto Rico hospitals only, while the capital Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico).

To adjust hospitals' capital payments for geographic variations in capital costs, we apply a GAF to both portions of the blended capital rate. The GAF is calculated using the operating IPPS wage index, and varies depending on the labor market area or rural area in which the hospital is located. We use the Puerto Rico wage index to determine the GAF for the Puerto Rico part of the capital-blended rate and the national wage index to determine the GAF for the national part of the blended capital rate.

Because we implemented a separate GAF for Puerto Rico in FY 1998, we also apply separate budget neutrality adjustments for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality factor for DRG reclassifications and recalibration nationally and for Puerto Rico. The proposed budget neutrality adjustments for the proposed national GAF and for the proposed Puerto Rico GAF, and the proposed budget neutrality factor for proposed MS–DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) is discussed above in section III.A.3. of this Addendum.

In computing the payment for a particular Puerto Rico hospital, the Puerto Rico portion of the capital rate (25 percent) is multiplied by the Puerto Rico-specific GAF for the labor market area in which the hospital is located, and the national portion of the capital rate (75 percent) is multiplied by the national GAF for the labor market area in which the hospital is located (which is computed from national data for all hospitals in the United States and Puerto Rico).

For FY 2012, the special capital rate for hospitals located in Puerto Rico was $203.86 (76 FR 51805). As discussed in section V.C.3. of the preamble of this proposed rule, we are not proposing to make any additional adjustments for the effect of documentation and coding that did not reflect real changes in case-mix to the capital Puerto Rico-specific rate for FY 2013. Therefore, with the changes we are proposing to make to the other factors used to determine the proposed capital rate, the proposed FY 2013 special capital rate for hospitals in Puerto Rico is $206.82.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2013

For purposes of calculating payments for each discharge during FY 2013, the capital standard Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2013 are in section II.A. of this Addendum. For FY 2013, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $27,425.

Currently, as provided in § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021), we rebased and revised the CIPI to a FY 2006 base year to reflect the more current structure of capital costs in hospitals. A complete discussion of this rebasing is provided in section IV. of the preamble of that final rule.

2. Forecast of the CIPI for FY 2013

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2012), we are forecasting the FY 2006-based CIPI to increase 1.3 percent in FY 2013. This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 1.9 percent increase in other capital expense prices in FY 2013, partially offset by a projected 2.2 percent decline in vintage-weighted interest expenses in FY 2013. The weighted average of these three

factors produces the proposed 1.3 percent increase for the FY 2006-based CIPI as a whole in FY 2013.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages

Historically, hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. An annual per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount for that period was multiplied by the Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to all categories of excluded providers (rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and cancer hospitals).

Payments for services furnished in children's hospitals and cancer hospitals that are excluded from the IPPS continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

In this proposed rule, we are proposing that the FY 2013 rate-of-increase percentage for updating the target amounts for cancer and children's hospitals and RNHCIs be the estimated percentage increase in the FY 2013 IPPS operating market basket, in accordance with applicable regulations at § 413.40. In this proposed rule, the estimated percentage increase in the FY 2013 IPPS operating market basket is estimated to be 3.0 percent. We also are proposing to use the most recent data available to determine the estimated percentage increase for the FY 2013 IPPS operating market basket. Based on IHS Global Insight, Inc.'s first quarter 2012 forecast, with historical data through the 2011 fourth quarter, the IPPS operating market basket update is 3.0 percent for FY 2013. Therefore, for cancer and children's hospitals and RNHCIs, the proposed FY 2013 rate-of-increase percentage that would be applied to the FY 2012 target amounts in order to determine the proposed FY 2013 target amount is 3.0 percent.

IRFs, IPFs, and LTCHs were previously paid under the reasonable cost methodology. However, the statute was amended to provide for the implementation of prospective payment systems for IRFs, IPFs, and LTCHs. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provide transitioning periods of varying lengths of time during which a portion of the prospective payment is based on cost-based reimbursement rules under 42 CFR Part 413 (certain providers do not receive a transitioning period or may elect to bypass the transition as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that all of the various transitioning periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2013. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2013

A. Proposed LTCH PPS Standard Federal Rate for FY 2013

1. Background

In section VII. of the preamble of this proposed rule, we discuss our proposed changes to the payment rates, factors, and specific policies under the LTCH PPS for FY 2013.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Thus, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at §§ 412.523(c)(3)(iv) through (c)(3)(vii). For FY 2012, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by section 1886(m)(3)(A) of the Act.

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.D.2.d. of the preamble of this proposed rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.D.2.d. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For FY 2012, consistent with our historical practice, we established an update to the LTCH PPS standard Federal rate based on the full estimated LTCH PPS market basket increase of 2.9 percent, the 1.1 percentage point reductions required by sections 1886(m)(3)(A)(i) and (m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(viii) of the regulations, we established an annual update of 1.8 percent to the standard Federal rate for FY 2012 (76 FR 51769 through 51771 and 51807).

In this proposed rule, for FY 2013, as discussed in greater detail in section VII.D.2. of the preamble of this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal rate based on the full estimated increase in the proposed LTCH PPS market basket, less the MFP adjustment consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act. Specifically, in this proposed rule, based on the best available data, we are proposing an annual update to the standard Federal rate of 2.1 percent, which is based on the full estimated increase in the proposed LTCH PPS market basket of 3.0 percent, less the proposed MFP adjustment of 0.8 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act.

2. Development of the Proposed FY 2013 LTCH PPS Standard Federal Rate

We continue to believe that the annual update to the LTCH PPS standard Federal rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. Consistent with our historical practice, we are proposing to apply the annual update to the LTCH PPS standard Federal rate from the previous year. In determining the proposed standard Federal rate for FY 2013, we also are proposing to make certain regulatory adjustments. Specifically, we are proposing to make a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3), as discussed in greater detail in section VII.E.4. of the preamble of this proposed rule (which would not be applicable to payments for discharges occurring prior to December 29, 2012, consistent with the statute.) In addition, in determining the proposed FY 2013 standard Federal rate, we are proposing to apply a budget neutrality adjustment for the proposed changes to the area wage adjustment (that is, proposed changes to the wage data and labor-related share) in accordance with § 412.523(d)(4).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51771 and 51807), we established an annual update to the LTCH PPS standard Federal rate of 1.8 percent for FY 2012 based on the full estimated LTCH PPS market basket increase of 2.9 percent, less the MFP adjustment of 1.0 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(viii), we established an annual update to the standard Federal rate for FY 2012 of 1.8 percent. That is, we applied an update factor of 1.018 to the FY 2011 Federal rate of $39,599.95 to determine the FY 2012 standard Federal rate. Furthermore, for FY 2012, we applied an area wage level budget neutrality factor of 0.99775 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, we established a standard Federal rate for FY 2012 of $40,222.05 (calculated as $39,599.95 × 1.018 × 0.99775), which is applicable to LTCH PPS discharges occurring on or after October 1, 2011, through September 30, 2012.

In this proposed rule, for FY 2013, as noted above and as discussed in greater detail in section VII.D.2. of the preamble of this proposed rule, consistent with our historical practice, we are proposing to establish an annual update to the proposed LTCH PPS standard Federal rate of 2.1 percent, based on the full estimated increase in the proposed LTCH PPS market basket of 3.0 percent less the proposed MFP adjustment of 0.8 percentage point consistent with section 1886(m)(3)(A)(i) and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Furthermore, as discussed in section VII.E.4. of the preamble of this proposed rule, in determining the proposed standard Federal rate for FY 2013, we are proposing to make a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) (which would not be applicable to payments for discharges occurring prior to December 29, 2012, consistent with the statute).

In this proposed rule, under proposed § 412.523(c)(3)(ix)(A), we are proposing to apply a factor of 1.021 to the FY 2012 standard Federal rate of $40,222.05 (as established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51807)) to determine the proposed FY 2013 standard Federal rate. In addition, as discussed in section VII.E.4. of the preamble of this proposed rule, the standard Federal rate would be further adjusted by the proposed one-time prospective adjustment factor for FY 2013 of 0.98734 under proposed § 412.523(d)(3)(ii). However, consistent with the statute, we are proposing at § 412.523(c)(3)(ix)(B) that, for payments for discharges occurring on or after October 1, 2012, and before December 29, 2012, payments are based on the standard Federal rate in paragraph (c)(3)(ix)(A) of this section without regard to the one-time prospective adjustment provided for under proposed § 412.523(d)(3)(ii). In addition, as discussed in greater detail in section V.B.5. of this Addendum, for FY 2013, we are proposing to apply an area wage level budget neutrality factor of 0.99903 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Consequently, in this proposed rule, under proposed § 412.523(c)(3)(ix)(A), we are proposing to establish a standard Federal rate for FY 2013 of $40,507.48 (calculated as $40,222.05 × 1.021 × 0.98734 × 0.99903). Furthermore, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012 and on or before December 28, 2012, would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88 (calculated as $40,507.48 divided by 0.98734).

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2013

1. Background

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act. For additional information on the development and initial implementation of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56017 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Geographic Classifications/Labor Market Area Definitions

In establishing an adjustment for area wage levels, the labor-related portion of a LTCH's Federal prospective payment is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located (67 FR 56015 through 56019). Specifically, the application of the LTCH PPS area wage level adjustment at § 412.525(c) is made on the basis of the location of the LTCH in either an urban area or a rural area as defined in § 412.503. Currently under the LTCH PPS at § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (which would include a metropolitan division, where applicable) as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area.

Currently, the labor market area definitions used under the LTCH PPS are based on the Executive OMB's CBSA designations, which are based on 2000 Census data (as adopted in the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185)). We adopted this policy because we believe that the CBSA-based labor market area definitions will ensure that the LTCH PPS wage index adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We note that these are the same CBSA-based designations currently used for acute care hospitals under the IPPS at § 412.64(b) (69 FR 49026 through 49034). (For further discussion of the CBSA-based labor market area (geographic classification) definitions currently used under the LTCH PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191).) Each year, we update the LTCH PPS CBSA-based labor market area definitions to reflect any changes OMB has made to the CBSA designations (73 FR 26812 through 26814; 74 FR 44023 through 44204; and 75 FR 50444 through 50445).

In OMB Bulletin No. 10–2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. We adopted those changes under the LTCH PPS for FY 2011 in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444 through 50445), and adopted their continued use for FY 2012 in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51808). In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data. Therefore, in this proposed rule, for FY 2013 wage index, we are proposing to continue to use the same labor market areas that we adopted for FY 2012 (76 FR 51808).

3. Proposed LTCH PPS Labor-Related Share

Under the adjustment for differences in area wage levels at § 412.525(c), the labor-

related share of a LTCH's Federal prospective payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-Related Services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket.

For FY 2012, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2008-based rehabilitation, psychiatric, and long-term care hospital (RPL) market basket. Accordingly, the current LTCH PPS labor-related share is based on the relative importance of the labor-related share of operating costs and capital costs of the RPL market basket based on FY 2008 data, as those were the best available data at that time that reflected the cost structure of LTCHs. For FY 2012, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808), we established a labor-related share of 70.199 percent based on the best available data at that time for the FY 2008-based RPL market basket for FY 2012. (Additional background information on the historical development of the labor-related share under the LTCH PPS and the development of the RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830).)

As discussed in section VII.C. of the preamble of this proposed rule, we are proposing to revise and rebase the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. Consistent with this proposal, we are proposing to determine the labor-related share for FY 2013 as the sum of the proposed FY 2013 relative importance of each labor-related cost category of the proposed FY 2009-based LTCH-specific market basket. Consistent with the current labor-related share determined from the relative importance of each labor-related cost category of the FY 2008-based RPL market basket, we are proposing to determine the LTCH PPS labor-related share for FY 2013 based on the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-Related Services) and the labor-related share of capital costs of the proposed LTCH-specific market basket based on FY 2009 data, as we believe these are currently the best data available to reflect the cost structure of LTCHs.

In this proposed rule, we are proposing a labor-related share under the LTCH PPS for FY 2013 based on IGI's first quarter 2012 forecast of the proposed FY 2009-based LTCH-specific market basket for FY 2013, as these are the most recent available data at this time that reflect the cost structure of LTCHs. As discussed in greater detail in section VII.C.3.f. of this preamble, the sum of the proposed relative importance for FY 2013 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All-Other: Labor-Related Services) is 58.978 percent and the proposed labor-related share of capital costs is 4.239 percent. Therefore, in this proposed rule, under the authority set forth in section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish a labor-related share of 63.217 percent (58.978 percent plus 4.239 percent) under the LTCH PPS for FY 2013, which would be effective for discharges occurring on or after October 1, 2012, and through September 30, 2013. Consistent with our historical practice of using the best data available, we also are proposing that if more recent data become available to determine the labor-related share used under the LTCH PPS for FY 2013, we would use those data for determining the FY 2013 LTCH PPS labor-related share in the final rule. (For additional details on the development of the proposed LTCH PPS labor-related share for FY 2013, we refer readers to section VII.C.3.f. of the preamble of this proposed rule.)

4. Proposed LTCH PPS Wage Index for FY 2013

Historically, under the LTCH PPS, we have established LTCH PPS wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider.

In the FY 2012 LTCH PPS final rule (76 FR 51808 through 51809), we calculated the FY 2012 LTCH PPS wage index values using the same data used for the FY 2012 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2008), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2012 LTCH PPS wage index values consistent with the urban and rural geographic classifications (labor market areas) and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). This IPPS wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus or campuses are located. We also continued to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable wage index values under the LTCH PPS for FY 2013, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2009, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2009 data because these data are the most recent complete data available. These are the same data used to compute the proposed FY 2012 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. (For our rationale for using IPPS hospital wage data as a proxy for determining the wage index values used under the LTCH PPS, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44024 through 44025).)

The proposed FY 2013 LTCH PPS wage index values we are presenting in this proposed rule are computed consistent with the urban and rural geographic classifications (labor market areas) discussed above in section V.B.2. of the Addendum to this proposed rule and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus or campuses are located (as discussed in section III.D. of the preamble of this proposed rule). Furthermore, in determining the proposed FY 2013 LTCH PPS wage index values in this proposed rule, we are proposing to continue to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

Specifically, we established a methodology for determining LTCH PPS wage index values for areas that have no IPPS wage data in the RY 2009 LTCH PPS final rule, and we are proposing to continue to use this methodology for FY 2013. (We refer readers to 73 FR 26817 through 26818 for an explanation of and rationale for our policy for determining LTCH PPS wage index values for areas that have no IPPS wage data.)

There are currently no LTCHs located in labor areas without IPPS hospital wage data (or IPPS hospitals) for FY 2013. However, we calculate LTCH PPS wage index values for these areas using our established methodology in the event that, in the future, a LTCH should open in one of those areas. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2009 IPPS wage data that we are proposing to use to determine the proposed FY 2013 LTCH PPS wage index values in this proposed rule, there are no IPPS hospital wage data for the urban area Hinesville-Fort Stewart, GA (CBSA 25980). Consistent with the methodology discussed above, we are proposing to calculate the FY 2013 wage index value for CBSA 25980 as

the average of the proposed wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet). We note that, as IPPS wage data are dynamic, it is possible that rural areas without IPPS hospital wage data will vary in the future.

Based on the FY 2009 IPPS wage data that we are proposing to use to determine the proposed FY 2013 LTCH PPS wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, for this proposed rule, it is not necessary to propose to use our established methodology to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data. We note that, as IPPS wage data are dynamic, it is possible that rural areas without IPPS hospital wage data will vary in the future. In addition, we are proposing that if there are rural areas without IPPS hospital wage data based on the updated data, we would use our established methodology to calculate a LTCH PPS wage index value for such rural areas with no IPPS wage data in the final rule.

The proposed FY 2013 LTCH wage index values that would be applicable for LTCH discharges occurring on or after October 1, 2012, through September 30, 2013, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site.

5. Proposed Budget Neutrality Adjustment for Changes to the Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809), under § 412.525(c)(2), we established that any changes to the wage index values or labor-related share will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected, that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that will be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment are budget neutral such that any changes to the wage index values or labor-related share will not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we established that we will apply an area wage level adjustment budget neutrality factor in determining the standard Federal rate and we also established a methodology for calculating an area wage level adjustment budget neutrality factor.

For FY 2013, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the standard Federal rate to account for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine a proposed area wage level adjustment budget neutrality factor that is applied to the standard Federal rate under at § 412.523(d)(4) for FY 2013 using the following methodology:

Step 1—We simulate estimated aggregate LTCH PPS payments using the FY 2012 wage index values (as established in Tables 12A and 12B listed in the Addendum to the FY 2012 IPPS/LTCH PPS final rule and available on the Internet) and the FY 2012 labor-related share of 70.199 percent (as established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51767 and 51808).

Step 2—We simulate estimated aggregate LTCH PPS payments using the proposed FY 2013 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available on the Internet) and the proposed FY 2013 labor-related share of 63.217 percent (based on the latest available data as discussed in section VII.C.3.f. of this preamble).

Step 3—We calculate the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2012 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS payments using the proposed FY 2013 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2013.

Step 4—We then apply the proposed FY 2013 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2013 LTCH PPS standard Federal rate after the application of the proposed FY 2013 annual update (discussed in section V.A.2. of the Addendum to this proposed rule).

For this proposed rule, using the steps in the methodology described above, we determined a proposed FY 2013 area wage level adjustment budget neutrality factor of 0.99903. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2013 LTCH PPS standard Federal rate, we applied a proposed area wage level adjustment budget neutrality factor of 0.99903, in accordance with § 412.523(d)(4). Accordingly, the proposed FY 2013 LTCH PPS standard Federal rate shown in Table 1E of the Addendum to this proposed rule reflects this proposed adjustment factor.

C. Proposed LTCH PPS Cost-of-Living Adjustment for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), we established a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States (67 FR 56022). Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels described above.

As we discuss in section VII.D.4. of the preamble of this proposed rule, historically, we have used the most recent updated COLA factors obtained from the OPM Web site at *http://www.opm.gov/oca/cola/rates.asp* to adjust the payments for LTCHs in Alaska and Hawaii. Recent statutory changes transition the Alaska and Hawaii COLAs to locality pay (phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of October 28, 2009, and then proportionately reduced to reflect the phase-in of locality). As stated previously, we do not believe it is appropriate to use either the 2010 or 2011 reduced factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii.

We believe it was appropriate to use ''frozen'' COLA factors to adjust payments in FY 2012 while we explored alternatives for updating the COLA adjustment in the future. As we discuss in greater detail in section VII.D.4. of the preamble of this proposed rule, we are proposing to continue to use the same ''frozen'' COLA factors used in FY 2012 for FY 2013. Furthermore, we are proposing to update the COLA factors for Alaska and Hawaii beginning in FY 2014 based on a comparison of the growth in the CPIs for Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). (For additional details on our proposal to update the COLA factors for Alaska and Hawaii beginning in FY 2014, we refer readers to section VII.D.4. of the preamble of this proposed rule.)

In this proposed rule, for FY 2013, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, we are proposing to use the same COLA factors used to adjust payments in FY 2012 (which are based on OPM's 2009 COLA factors) by multiplying the nonlabor-related portion of the standard Federal payment rate by the proposed factors listed in the chart below.

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE LTCH PPS FOR FY 2013

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE LTCH PPS FOR FY 2013—Continued

All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. Background

Under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in the regulations at § 412.525(a), we established an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. We refer to these cases as high-cost outliers (HCOs). Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be incurred when treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. We set the outlier threshold before the beginning of the applicable rate year so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS.

Under § 412.525(a) in the regulations (in conjunction with § 412.503), we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted LTCH PPS payment for the MS–LTC–DRG plus a fixed-loss amount. Specifically, in accordance with § 412.525(a)(3) (in conjunction with § 412.503), we make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the patient case and the outlier threshold, which is the sum of the adjusted Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital will incur under the outlier policy for a case with unusually high costs. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the LTCH PPS HCO policy, the LTCH's loss is limited to the fixed-loss amount and a fixed percentage of costs above the outlier threshold (adjusted MS–LTC–DRG payment plus the fixed-loss amount). The fixed percentage of costs is called the marginal cost factor. We calculate the estimated cost of a case by multiplying the Medicare allowable covered charge by the hospital's overall hospital cost-to-charge ratio (CCR).

Under the LTCH PPS HCO policy at § 412.525(a), we determine a fixed-loss amount, that is, the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent Provider-Specific File (PSF) (or from the applicable statewide average CCR if a LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining payments for HCO and SSO cases under the LTCH PPS, at § 412.525(a) and § 412.529, respectively. Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for both HCO and SSO cases (to determine the estimated cost of the case at § 412.529(d)(2)), we are discussing the determination of CCRs under the LTCH PPS for both of these types of cases simultaneously.

In determining both HCO payments (at § 412.525(a)) and SSO payments (at § 412.529), we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. In general, we use the LTCH's overall CCR, which is computed based on either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period, in accordance with § 412.525(a)(4)(iv)(B) and § 412.529(f)(4)(ii) for HCOs and SSOs, respectively. (We note that, in some instances, we use an alternative CCR, such as the statewide average CCR in accordance with the regulations at § 412.525(a)(4)(iv)(C) and § 412.529(f)(4)(iii), or a CCR that is specified by CMS or that is requested by the hospital under the provisions of the regulations at § 412.525(a)(4)(iv)(A) and § 412.529(f)(4)(i).) Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs. Therefore, we compute a single ''overall'' or ''total'' LTCH-specific CCR based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total charges. Specifically, a LTCH's CCR is calculated by dividing a LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) by its total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, a LTCH is assigned the applicable statewide average CCR if, among other things, a LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This is because CCRs above this threshold are most likely due to faulty data reporting or entry, and, therefore, CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Thus, under our established policy, generally, if a LTCH's calculated CCR is above the applicable ceiling, the applicable LTCH PPS statewide average CCR is assigned to the LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

In accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2011 update of the PSF, we are proposing to establish a total CCR ceiling of 1.210 under the LTCH PPS that would be effective for discharges occurring on or after October 1, 2012, through September 30, 2013. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data became available, we would use such data to establish a total CCR ceiling for FY 2013 in the final rule.

c. Proposed LTCH Statewide Average CCRs

Our general methodology established for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling (described above) because it is based on ''total'' IPPS CCR data. Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C) and the SSO policy at § 412.529(f)(4)(iii), the fiscal intermediary or MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for a LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the fiscal intermediary or MAC may consider in determining a LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as a LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data and using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2011 update of the PSF, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2012, through September 20, 2013, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet). Consistent with our historical policy of using the best available data, we

also are proposing that if more recent data become available, we would use such data to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for FY 2013 in the final rule.

All areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS.

In addition, consistent with our existing methodology, in determining the proposed urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, in this proposed rule, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We use this proxy because we believe that the CCR data on the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of LTCH HCO and SSO Payments

We note that under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(D) and the LTCH PPS SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases, respectively, are subject to reconciliation. Specifically, any reconciliation of outlier payments is based on the CCR that is calculated based on a ratio of cost-to-charge data computed from the relevant cost report determined at the time the cost report coinciding with the discharge is settled. For additional information, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4) as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Establishment of the Proposed LTCH PPS Fixed-Loss Amount for FY 2013

When we implemented the LTCH PPS, as discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56026), under the broad authority of section 123 of the BBRA as amended by section 307(b) of BIPA, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS. To determine the fixed-loss amount, we estimate outlier payments and total LTCH PPS payments for each case using claims data from the MedPAR files. Specifically, to determine the outlier payment for each case, we estimate the cost of the case by multiplying the Medicare covered charges from the claim by the LTCH's CCR. Under § 412.525(a)(3) (in conjunction with § 412.503), if the estimated cost of the case exceeds the outlier threshold, we make an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (that is, the sum of the adjusted Federal prospective payment for the MS–LTC–DRG and the fixed-loss amount).

In this proposed rule, we are proposing to continue to use our existing methodology to calculate the proposed fixed-loss amount for FY 2013 (based on the data and the proposed rates and policies presented in this proposed rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. (For additional detail on the rationale for setting the HCO payment ''target'' at 8 percent of total estimated LTCH PPS payments, we refer readers to the to the FY 2003 LTCH PPS final rule (67 FR 56022 through 56024.) Consistent with our historical practice of using the best data available, in determining the proposed fixed-loss amount for FY 2013, we use the most recent available LTCH claims data and CCR data at this time. Specifically, for this proposed rule, we are using LTCH claims data from the December 2011 update of the FY 2011 MedPAR file and CCRs from the December 2011 update of the PSF to determine a proposed fixed-loss amount that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments in FY 2013 because these data are the most recent complete LTCH data available at this time. Consistent with the historical practice of using the best available data, we also are proposing that if more recent LTCH claims data become available, we would use them for determining the fixed-loss amount for FY 2013 in the final rule.

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we established a fixed-loss amount of $17,931 for FY 2012. For this proposed rule, we are proposing to establish a fixed-loss amount of $15,728 for FY 2013. Thus, we are proposing to make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the proposed outlier threshold (the sum of the proposed adjusted Federal LTCH payment for the proposed MS–LTC–DRG and the proposed fixed-loss amount of $15,728). We also note that the proposed fixed-loss amount of $15,728 for FY 2013 is lower than the FY 2012 fixed-loss amount of $17,931. Based on our payment simulations using the most recent available data at this time, the proposed decrease in the fixed-loss amount for FY 2013 is necessary to maintain the existing requirement that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments. (For further information on the existing 8 percent HCO ''target'' requirement, as noted above, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024.) Maintaining the fixed-loss amount at the current level would result in HCO payments that are less than the current regulatory 8-percent requirement because a higher fixed-loss amount would result in fewer cases qualifying as outlier cases. In addition, maintaining the higher fixed-loss amount would result in a decrease in the amount of the additional payment for an HCO case because the maximum loss that a LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be larger. For these reasons, we believe that proposing to lower the fixed-loss amount is appropriate and necessary to maintain that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments as required under § 412.525(a).

4. Application of Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case. In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the fixed-loss amount), the discharge is eligible for payment as an HCO. Thus, for an SSO case in FY 2013, the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed fixed-loss amount of $15,728 and the amount paid under the SSO policy as specified in § 412.529).

E. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2013

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal rate. Under § 412.525(c), the standard Federal rate is adjusted to account for differences in area wages by multiplying the labor-related share of the standard Federal rate by the applicable LTCH PPS wage index (proposed FY 2013 values shown in Tables 12A and 12B listed in section VI. of the Addendum of this proposed rule and available via the Internet). The standard Federal rate is also adjusted to account for the higher costs of hospitals in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal rate by the applicable cost-of-living factor (proposed FY 2013 factors shown in the chart in section V.C. of the Addendum of this proposed rule) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish a proposed standard Federal rate for FY 2013 of $40,507.48 (however, payment for discharges occurring on or after October 1, 2012, and before December 29, 2012 would not reflect that proposed adjustment consistent with the statute, and instead would be paid based on a standard Federal rate of $41,026.88), as discussed above in section V.A.2. of the Addendum of this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS Federal standard rate for FY 2013 in the following example:

Example: During FY 2013, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974) and discharged on January 1, 2013. The proposed FY 2013 LTCH PPS wage index value for CBSA 16974 is 1.0623 (Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet). The Medicare patient is classified into proposed MS–LTC–DRG 28 (Spinal Procedures with MCC),

which has a proposed relative weight for FY 2013 of 1.5986 (Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet).

To calculate the LTCH's proposed total adjusted Federal prospective payment for this Medicare patient in FY 2013, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2013 standard Federal rate ($40,507.48) by the proposed labor-related share (63.217 percent) and the proposed wage index value (1.0623). This wage-adjusted amount is then added to the nonlabor-related portion of the unadjusted proposed standard Federal rate (36.783 percent; adjusted for cost of living, if applicable) to determine the adjusted Federal rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (1.5886) to calculate the total adjusted proposed Federal LTCH PPS prospective payment for FY 2013 ($67,305.58). The table below illustrates the components of the calculations in this example.

Proposed Unadjusted Standard Federal Prospective Payment Rate.	$40,507.48
Proposed Labor-Related Share.	× 0.63217
Proposed Labor-Related Portion of the Federal Rate.	= $25,607.61
Proposed Wage Index (CBSA 16974).	× 1.0623
Proposed Wage-Adjusted Labor Share of Federal Rate.	= $27,202.96
Proposed Nonlabor-Related Portion of the Federal Rate ($40,507.48 x 0.36783).	+ $14,899.87
Proposed Adjusted Federal Rate Amount.	= $42,102.83
Proposed MS–LTC–DRG 28 Relative Weight.	× 1.5986
Total Proposed Adjusted Federal Prospective Payment.	= $67,305.58

VI. Tables Referenced in This Proposed Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FY 2012, for the FY 2013 rulemaking cycle, the IPPS and LTCH tables will not be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings and will be available only through the Internet. Specifically, IPPS tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, 6A, 6B, 6C, 6D, 6E, 6F, 6G, 6I, 6I.1, 6.I.2, 6J, 6J.1, 6K, 7A, 7B, 8A, 8B, 9A, 9C, 10 and new tables 15 and 16 and LTCH PPS tables 8C, 11, 12A, 12B, 13A, and 13B will be available only through the Internet. IPPS tables 1A, 1B, 1C, and 1D, and LTCH PPS table 1E, displayed at the end of this section, will continue to be published in the **Federal Register** as part of the annual proposed and final rules. As discussed in section II.G.9. of the preamble of this proposed rule, for FY 2013, there were no changes to the ICD–9–CM coding system, effective October 1, 2012, due to the partial code freeze in anticipation of the transition to the ICD–10 coding system or for new technology. Therefore, there will be no new, revised, or deleted diagnosis and procedure codes effective October 1, 2012, that are usually announced in Tables 6A (New Diagnosis Codes), 6B (New Procedure Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). Therefore, these tables will not be published as part of this FY 2013 rulemaking cycle. As discussed in section IV.E. of this proposed rule, effective FY 2013 and forward, the low-volume hospital definition and payment adjustment methodology under section 1886(d)(12) of the Act will return to the pre-Affordable Care Act definition and payment adjustment methodology (we refer readers to section IV.E. for complete details on the low-volume hospital payment adjustment). Therefore, we are no longer including a table (previously Table 14) in this proposed rule that lists the low volume payment adjustments.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Ing Jye Cheng at (410) 786–4548.

The following IPPS tables for this FY 2013 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp*. Click on the link on the left side of the screen titled, ''FY 2013 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''.

Table 2.—Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2011; Proposed Hospital Wage Indexes for Federal Fiscal Year 2013; Hospital Average Hourly Wages for Federal Fiscal Years 2011 (2007 Wage Data), 2012(2008 Wage Data), and 2013 (2009 Wage Data); and 3–Year Average of Hospital Average Hourly Wages

Table 3A.—Proposed FY 2013 and 3–Year Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—Proposed FY 2013 and 3–Year Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA

Table 4A.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State—FY 2013

Table 4B.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2013

Table 4C.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2013

Table 4D.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Proposed Frontier State Floor Wage Index[1]; Urban Areas With Acute Care Hospitals Receiving the Proposed Statewide Rural Floor Wage Index—FY 2013

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2013

Table 4F.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2013

Table 4J.—Proposed Out-Migration Adjustment for Acute Care Hospitals—FY 2013

Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2013

Table 6G—Additions to the CC Exclusions List—FY 2013

Table 6I.—Proposed Complete MCC List—FY 2013

Table 6I.2.—Proposed Deletions to the MCC List—FY 2013

Table 6J.—Proposed Complete CC List—FY 2013

Table 6J.1.—Proposed Additions to the CC List—FY 2013

Table 6K.—Proposed Complete List of CC Exclusions—FY 2013

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2011 MedPAR Update—December 2011 GROUPER V29.0 MS–DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2011 MedPAR Update—December 2011 GROUPER V30.0 MS–DRGs

Table 8A.—Proposed FY 2013 Statewide Average Operating Cost to Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2013 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations—FY 2013

Table 9C.—Hospitals Redesignated as Rural Under Section 1886(d)(8)(E) of the Act—FY 2013

Table 10.—Proposed New Technology Add-On Payment Thresholds for Applications for FY 2014

Table 15.—FY 2013 Proposed Readmissions Adjustment Factors

Table 16.—Proposed Hospital Inpatient Value-Based Purchasing Program (VBP) Program Adjustment Factors for FY 2013

The following LTCH PPS tables for this FY 2013 proposed rule are available only through the Internet on the CMS Web site at *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1588–P.

Table 8C.—Proposed FY 2013 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for Discharges Occurring from October 1, 2012 through September 30, 2013 under the LTCH PPS

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2012 through September 30, 2013

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring From October 1, 2012 through September 20, 2013

Table 13A.—Composition of Proposed Low-Volume Quintiles for MS–LTC–DRGs—FY 2013

Table 13B.—Proposed No-Volume MS–LTC–DRG Crosswalk for FY 2013

TABLE 1A—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.8 PERCENT LABOR SHARE/31.2 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2013

Full update (2.1 percent)		Reduced update (0.1 percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,664.03	$1,661.59	$3,592.26	$1,629.04

TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2013

Full update (2.1 percent)		Reduced update (0.1 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,301.88	$2,023.74	$3,237.21	$1,984.09

TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR—FY 2013

	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National	$3,664.03	$1,661.59	$3,301.88	$2,023.74
Puerto Rico	1,583.10	966.17	1,580.55	968.72

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2013

	Rate
National	$424.42
Puerto Rico	206.82

TABLE 1E—PROPOSED LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE—FY 2013

	Rate
Standard Federal Rate*	$40,507.48

*Consistent with section 114(c)(4) of the MMSEA as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88 (calculated as $40,507.48 divided by 0.98734).

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2013 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this proposed rule, will result in an estimated $904 million increase in proposed FY 2013 operating payments (or 0.9 percent change) and an estimated $8 million decrease in proposed FY 2013 capital payments (or -0.1 percent change). The proposed impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by $100 million in FY 2013 relative to FY 2012.

Our operating impact estimate includes the proposed 0.2 percent documentation and coding adjustment applied to the IPPS standardized amounts (which accounts for the proposed −2.7 percent documentation and coding adjustment and 2.9 percent adjustment to restore the one-time recoupment adjustment made to the national standardized amount for FY 2012). In addition, our operating impact estimate includes the proposed 2.1 percent hospital update to the standardized amount (which includes the 3.0 percent proposed market basket update less 0.8 percentage point for the proposed multifactor productivity adjustment and less 0.1 percentage point required under the Affordable Care Act). The proposed estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. The proposed

rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant.

B. Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

C. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe the changes in this proposed rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2013, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 32 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, only the 45 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of March 2012, there are 3,405 IPPS acute care hospitals to be included in our analysis. This represents about 67 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,349 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. There are also 1,232 IPPS-excluded hospitals and 2,090 IPPS-excluded hospital units. These IPPS-excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, and cancer hospitals, which are paid under separate payment systems. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts for these IPPS-excluded hospitals and units are not included in this proposed rule. The proposed impact of the update and policy changes to the LTCH PPS for FY 2013 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2012, there were 3,337 hospitals and hospital units excluded from the IPPS. Of these, 78 children's hospitals, 11 cancer hospitals, and 17 RNHCIs are being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. The remaining providers, 230 rehabilitation hospitals and 906 rehabilitation units, and 442 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 469 psychiatric hospitals and 1,148 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated above, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.J. of this Appendix.

In the past, certain hospitals and units excluded from the IPPS have been paid based on their reasonable costs subject to limits as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Cancer and children's hospitals continue to be paid on a reasonable cost basis subject to TEFRA limits for FY 2013. For these hospitals (cancer and children's hospitals), consistent with the authority provided in section 1886(b)(3)(B)(ii) of the Act, the proposed update is the FY 2013 percentage increase in the IPPS operating market basket. In compliance with section 404 of the MMA, in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43930), we replaced the FY 2002-based IPPS operating and capital market baskets with the revised and rebased FY 2006-based IPPS operating and capital market baskets. Therefore, consistent with current law, based on IHS Global Insight, Inc.'s 2012 first quarter forecast, with historical data through the 2011 fourth quarter, we are estimating that the proposed FY 2013 update based on the IPPS operating market basket is 3.0 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently proposed to be 0.8 percentage point) and a 0.1 percentage point reduction to the market basket update resulting in a proposed 2.1 percent applicable percentage increase for IPPS hospitals. RNCHIs, children's hospitals and cancer hospitals are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40. Therefore, for RNHCIs, the proposed update is the same as for children's and cancer hospitals, which is the percentage increase in the FY 2013 IPPS operating market basket, estimated at 3.0 percent, without the reductions required under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with per-case cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that will not be reimbursed.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus 50 percent of the difference between its reasonable costs and 110 percent of the limit, not to exceed 110 percent of its limit. In addition, under the various provisions set forth in § 413.40, cancer and children's hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2013 for operating costs of acute care hospitals. The proposed FY 2013 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2013 operating payments will increase by 0.9 percent compared to FY 2012. In addition to the applicable percentage increase, this amount reflects the proposed FY 2013 adjustments for documentation and coding described in section II.D. of the preamble of this proposed rule: 0.2 percent for the IPPS national standardized amounts and -1.3 percent for the IPPS hospital-specific rates. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which will also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed

changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented below are taken from the FY 2011 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2011 MedPAR file, we simulated proposed payments under the operating IPPS given various combinations of payment parameters. As described above, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The proposed impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Proposed estimated payment impacts of the capital IPPS for FY 2013 are discussed in section I.I. of this Appendix.

We discuss the following changes below:

- The effects of the proposed application of the documentation and coding adjustment and applicable percentage increase (including the market basket update, the multifactor productivity adjustment and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- The effects of the proposed annual reclassification of diagnoses and procedures, full implementation of the MS–DRG system and 100 percent cost-based MS–DRG relative weights.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2009, compared to the FY 2008 wage data.
- The effects of the proposed recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act, including the wage and recalibration budget neutrality factors.
- The effects of the proposed geographic reclassifications by the MGCRB that will be effective in FY 2013.
- The effects of the proposed rural floor and imputed floor with the application of the national budget neutrality factor applied to the wage index, as required by the Affordable Care Act.
- The effects of the proposed frontier State wage index provision that requires that hospitals located in States that qualify as frontier States cannot have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the proposed implementation of section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.
- The effects of the proposed policies for implementation of the Hospital Readmissions Reduction Program under section 3025 of the Affordable Care Act, that adjusts hospital's base operating DRG amount by an adjustment factor to account for a hospital's excess readmissions.
- The effects of the expiration of the special payment status for MDHs under section 3124 of the Affordable Care Act under which MDHs that currently receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate will be paid based on the Federal standardized amount starting in FY 2013.
- The proposed total estimated change in payments based on the FY 2013 proposed policies relative to payments based on FY 2012 policies that include the applicable percentage increase of 2.1 percent (or proposed 3.0 percent market basket update with a proposed reduction of 0.8 percentage point for the multifactor productivity adjustment, and a 0.1 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2013 changes, our analysis begins with a FY 2012 baseline simulation model using: The proposed FY 2013 applicable percentage increase of 2.1 percent and the documentation and coding adjustment of 0.2 to the Federal standardized amount and the 1.3 percent documentation and coding adjustment to the hospital-specific rate; the FY 2012 MS–DRG GROUPER (Version 29.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2012 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 through FY 2014, the update factor will include a reduction of 2.0 percentage points for any hospital that does not submit quality data in a form and manner and at a time specified by the Secretary. (Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act.) At the time that this impact was prepared, 48 hospitals did not receive the full market basket rate-of-increase for FY 2012 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2013 using a reduced update for these 48 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2013.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2013 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each proposed change.

Our final comparison illustrates the proposed percent change in payments per case from FY 2012 to FY 2013. Three factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2013 using an applicable percentage increase of 2.1 percent. This includes our forecasted IPPS operating hospital market basket increase of 3.0 percent with a reduction of 0.8 percentage point for the proposed multifactor productivity adjustment and a 0.1 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements will receive an update of 0.1 percent (this update includes the 2.0 percentage point reduction for failure to submit these data)). Under section 1886(b)(3)(B)(iv) of the Act, the proposed updates to the hospital-specific amounts for SCHs are also equal to the applicable percentage increase, or 2.1 percent. In addition, we are proposing to update the Puerto Rico-specific amount by an applicable percentage increase of 2.1 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2012 to FY 2013 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2012 that are no longer reclassified in FY 2013. Conversely, payments may increase for hospitals not reclassified in FY 2012 that are reclassified in FY 2013.

A third significant factor is that we currently estimate that actual outlier payments during FY 2012 will be 6.0 percent of total MS–DRG payments. Our updated FY 2012 outlier estimate accounts for changes to the FY 2012 IPPS payments required under the Affordable Care Act. When the FY 2012 final rule was published, we projected FY 2012 outlier payments would be 5.1 percent of total MS–DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the higher than expected outlier payments during FY 2012 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current proposed estimates of FY 2012 payments per case to estimated proposed FY 2013 payments per case (with outlier payments projected to

equal 5.1 percent of total MS–DRG payments).

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2013. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,405 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,485 hospitals located in urban areas included in our analysis. Among these, there are 1,365 hospitals located in large urban areas (populations over 1 million), and 1,120 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 920 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' proposed FY 2012 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,500; 1,375; 1,125; and 905, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive DSH payments, or some combination of these two adjustments. There are 2,376 nonteaching hospitals in our analysis, 789 teaching hospitals with fewer than 100 residents, and 240 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next five rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 199 RRCs, 340 SCHs, 195 former MDHs, and 101 hospitals that are both SCHs and RRCs, and 17 hospitals that were former MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2009 or FY 2008 Medicare cost reports.

The next two groupings concern the proposed geographic reclassification status of hospitals. The first grouping displays all proposed urban hospitals that were reclassified by the MGCRB for FY 2013. The second grouping shows the proposed MGCRB rural reclassifications. The final category shows the impact of the proposed policy changes on the 18 cardiac hospitals.

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TABLE I.— IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2013

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
All Hospitals	3,405	2.2	0	0	0	0	0	0.1	0	-0.1	-0.3	0.9
By Geographic Location:												
Urban hospitals	2,485	2.3	0	0	0.1	-0.2	0	0.1	0	0	-0.3	1
Large urban areas	1,365	2.3	0	0.2	0.2	-0.3	0	0	0	0	-0.3	1.2
Other urban areas	1,120	2.3	0	-0.2	-0.1	-0.1	0.1	0.1	0	-0.1	-0.2	0.9
Rural hospitals	920	1.8	-0.1	-0.3	-0.3	2.1	-0.3	0	0.1	-0.9	-0.3	-0.5
Bed Size (Urban):												
0-99 beds	627	2.3	0	0.1	0.2	-0.6	0.2	0.2	0	-0.4	-0.2	1
100-199 beds	773	2.3	0	0.1	0.2	0	0.3	0	0	-0.1	-0.3	1.1
200-299 beds	448	2.3	0	0.1	0.1	-0.2	0	0.1	0	0	-0.3	1.2
300-499 beds	432	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1.2
500 or more beds	205	2.3	0	-0.1	0	-0.3	-0.1	0	0	0	-0.3	0.8
Bed Size (Rural):												
0-49 beds	317	1.8	-0.1	-0.3	-0.4	0.8	-0.3	0.1	0.3	-1.4	-0.3	-1.9
50-99 beds	346	1.7	-0.1	-0.3	-0.4	1.2	-0.3	0	0.2	-2.2	-0.3	-2.4
100-149 beds	152	1.8	-0.1	-0.3	-0.3	2.6	-0.3	0	0	-0.3	-0.4	0.3
150-199 beds	58	1.8	-0.1	-0.2	-0.3	2.3	-0.3	0.1	0	0	-0.3	0.6
200 or more beds	47	1.8	0	-0.2	-0.1	3	-0.3	0	0	0	-0.3	1.1

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Urban by Region:												
New England	120	2.3	0	1	1	0.7	3.1	0	0	0	-0.4	-0.4
Middle Atlantic	318	2.3	0	0	0	0.1	-0.2	0	0	0	-0.5	0.5
South Atlantic	377	2.3	0	-0.4	-0.4	-0.4	-0.4	0	0	0	-0.3	0.8
East North Central	396	2.3	0	0.1	0.2	-0.2	-0.4	0	0	0	-0.3	1.2
East South Central	151	2.3	0	-0.8	-0.7	-0.5	-0.3	0	0	0	-0.4	0.5
West North Central	165	2.2	0	0.6	0.6	-0.6	-0.4	0.7	0	-0.1	-0.2	1.8
West South Central	370	2.3	0	-0.2	-0.2	-0.6	-0.4	0	0	-0.1	-0.2	1.1
Mountain	157	2.1	0	-0.2	-0.2	-0.3	-0.1	0.2	0	0	-0.1	1.2
Pacific	380	2.3	-0.1	0.7	0.6	-0.2	0.9	0	0	0	-0.2	2.4
Puerto Rico	51	2.2	0	0.3	0.2	-0.8	0.2	0	0	0	0	1.7
Rural by Region:												
New England	23	1.9	-0.1	-0.1	-0.2	2.3	-0.4	0	0	-3.5	-0.1	-2.1
Middle Atlantic	69	1.6	-0.1	-0.2	-0.3	1.8	-0.3	0	0	-1.3	-0.3	-0.5
South Atlantic	164	1.9	-0.1	-0.6	-0.7	2.7	-0.3	0	0.1	-0.6	-0.4	-0.3
East North Central	120	1.7	0	-0.1	-0.1	1.5	-0.2	0	0.1	-1.7	-0.2	-0.9
East South Central	170	2.2	0	-0.4	-0.4	2.9	-0.4	0	0.1	-0.1	-0.4	-0.1
West North Central	98	1.2	0	-0.2	-0.2	1.2	-0.2	0.2	0.1	-1.2	-0.2	-0.7
West South Central	181	2	0	0	0	2.2	-0.3	0	0.2	-0.2	-0.5	-0.5
Mountain	65	1.2	0	0	0	0.5	-0.1	0.8	0	0	-0.1	0.6
Pacific	29	1.3	-0.1	-0.1	-0.2	1	-0.2	0	0	-0.1	-0.1	0

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Puerto Rico	1	2.2	0.7	0.8	1.4	-0.9	-0.4	0	0	0	0	3.7
By Payment Classification:												
Urban hospitals	2,500	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1
Large urban areas	1,375	2.3	0	0.2	0.2	-0.3	0	0	0	0	-0.3	1.1
Other urban areas	1,125	2.3	0	-0.2	-0.1	0	0.1	0.1	0	0	-0.2	1
Rural areas	905	1.8	0	-0.2	-0.2	1.7	-0.3	0	0.1	-1	-0.3	-0.5
Teaching Status:												
Nonteaching	2,376	2.2	0	-0.1	-0.1	0.3	0.1	0	0	-0.3	-0.3	0.7
Fewer than 100 residents	789	2.3	0	0.1	0.1	-0.1	-0.1	0.1	0	0	-0.3	1.1
100 or more residents	240	2.3	0	0.1	0.1	-0.2	0	0	0	0	-0.3	0.8
Urban DSH:												
Non-DSH	758	2.3	0	0.2	0.2	-0.2	0	0	0	-0.3	-0.3	0.5
100 or more beds	1,523	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1.1
Less than 100 beds	327	2.3	0	0	0.1	-0.1	0.2	0.1	0	-0.4	-0.2	1.2
Rural DSH:												
SCH	269	1.1	-0.1	0	-0.2	0.5	-0.1	0	0	0	-0.3	-0.8
RRC	210	1.9	0	-0.1	-0.1	2.6	-0.3	0	0	-0.5	-0.3	0.6
100 or more beds	32	2.3	-0.1	-0.4	-0.4	1.3	-0.4	0	0.2	-0.8	-0.5	-0.3
Less than 100 beds	286	2.3	0	-0.6	-0.6	1	-0.3	0.1	0.4	-2.2	-0.4	-2.6
Urban teaching and DSH:												
Both teaching and DSH	815	2.3	0	0	0.1	-0.3	-0.1	0.1	0	0	-0.3	1

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Teaching and no DSH	147	2.3	-0.1	0.5	0.4	-0.1	0.2	0	0.1	0	-0.3	0.7
No teaching and DSH	1,035	2.3	0	-0.1	-0.1	0	0.3	0	0	0	-0.3	1.3
No teaching and no DSH	503	2.3	0	0.1	0.1	-0.4	-0.1	0.1	0	0	-0.3	0.9
Special Hospital Types:												
RRC	199	2.3	0	0.1	0.2	3	-0.4	0.1	0	-0.8	-0.3	0.9
SCH	340	1.1	-0.1	-0.2	-0.3	0.3	0	0.1	0.1	0	-0.2	-0.4
Former MDH	195	2.3	0	-0.4	-0.4	0.4	-0.2	0	0.3	-6.1	-0.5	-7
SCH and RRC	101	1.2	-0.1	0.1	0	0.7	-0.1	0.1	0	0	-0.2	0.4
Former MDH and RRC	17	2.3	0.1	0.3	0.4	1.2	-0.4	0	0	-15.2	-0.3	-14.8
Type of Ownership:												
Voluntary	1,970	2.2	0	0.1	0.1	0	0	0.1	0	-0.1	-0.3	0.8
Proprietary	866	2.3	0.1	-0.3	-0.2	0.1	-0.1	0	0	-0.1	-0.3	1.1
Government	560	2.2	0	-0.2	-0.2	-0.1	-0.1	0	0	-0.1	-0.3	0.9
Medicare Utilization as a Percent of Inpatient Days:												
0-25	377	2.2	0	0.1	0.1	-0.3	0	0	0	0	-0.2	1.8
25-50	1,834	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1
50-65	968	2.2	0	0	0.1	0.7	0.1	0	0	-0.4	-0.3	0.4
Over 65	168	2.1	-0.1	-0.3	-0.3	0.6	0.1	0.1	0.1	-1.2	-0.5	-0.5

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Proposed FY 2013 Reclassifications by the Medicare Geographic Classification Review Board:												
All Reclassified Hospitals	755	2.2	0	0.2	0.2	2.2	0.3	0	0	-0.1	-0.3	0.9
Non-Reclassified Hospitals	2,650	2.3	0	-0.1	0	-0.7	-0.1	0.1	0	-0.1	-0.3	0.9
Urban Hospitals Reclassified	420	2.3	0	0.3	0.4	1.9	0.5	0	0	0	-0.4	1.1
Urban Nonreclassified Hospitals, FY 2013:	2,025	2.3	0	-0.1	0	-0.7	-0.1	0.1	0	0	-0.3	1
All Rural Hospitals Reclassified FY 2013:	335	1.8	0	-0.2	-0.2	3.1	-0.3	0	0	-0.5	-0.3	0.2
Rural Nonreclassified Hospitals FY 2013:	524	1.7	-0.1	-0.3	-0.4	-0.2	-0.3	0.1	0.3	-1.3	-0.3	-1.8
All Section 401 Reclassified Hospitals:	46	1.8	0	0.5	0.5	-0.6	-0.1	0	0	-2.6	-0.2	-1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	2	-0.1	-0.2	-0.2	2.9	-0.4	0	0	-3.1	-0.3	-2.4
Specialty Hospitals												
Cardiac specialty Hospitals	18	2.3	0.1	-0.2	-0.1	-0.8	0	0.6	0	0	-0.1	2.7

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2011, and hospital cost report data are from reporting periods beginning in FY 2009 and FY 2008.

[2] This column displays the payment impact of the proposed hospital rate update and documentation and coding adjustment including the 2.1 percent adjustment to the national standardized amount (the 3.0 percent proposed market basket update reduced by the 0.8 percentage point for the proposed multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the 0.2 percent documentation and coding adjustment to the national standardized amount (-2.7 documentation and coding adjustment and 2.9 percent return to the rate to account for the one-time documentation and coding recoupment from FY 2012). In addition, it displays the payment impact of the proposed hospital rate update of 2.1 percent and the proposed documentation and coding adjustment of -1.3 percent to the hospital-specific rate.

[3] This column displays the payment impact of the proposed changes to the Version 30.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2011 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.998546, in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2009 cost report data. This column displays the payment impact of the application of proposed the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 1.000563.

[5.] This column displays the combined payment impact of the proposed changes in Columns 3 through 4 and the proposed cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The proposed cumulative wage and recalibration budget neutrality factor of 0.999108 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

[6] Shown here are the proposed effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2013 payment impact of going from no reclassifications to the proposed reclassifications scheduled to be in effect for FY 2013. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.991436.

[7.] This column displays the proposed effects of the rural floor and imputed floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. This column does not reflect the alternative temporary methodology proposed beginning in FY 2013; we note that the impact of that proposal is discussed separately and would have a negligible impact on budget neutrality. The proposed rural floor and imputed floor budget neutrality factor is 0.992243.

[8] This column shows the proposed impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0.

[9.] This column displays the proposed impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

[10.] This column displays the impact of the expiration of MDH status, under section 3124 of the Affordable Care Act, a non-budget neutral payment provision.

[11.] This column displays the impact of the proposed implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a non-budget neutral provision that adjusts a hospital's payment for excess readmissions.

[12.] This column shows the proposed changes in payments from FY 2012 to FY 2013. It reflects the impact of the proposed FY 2013 hospital update, the proposed adjustments due to the documentation and coding. It also reflects proposed changes in hospitals' reclassification status in FY 2013 compared to FY 2012. It incorporates all of the changes displayed in Columns 2, 5, 6, 7, 8, 9, 10 and 11 (the changes displayed in Columns 3 and 4 are included in Column 5). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

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a. Effects of the Proposed Hospital Update and Proposed Documentation and Coding Adjustment (Column 2)

As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed hospital update, including the 3.0 percent proposed market basket update, the reduction of 0.8 percentage point for the proposed multifactor productivity adjustment, and the 0.1 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed FY 2013 documentation and coding adjustment of 0.2 percent on the national standardized amount, which includes the −2.7 percent prospective adjustment for documentation and coding and a 2.9 percent adjustment to restore the one-time recoupment adjustment made to the national standardized amount for FY 2012. As a result, we a proposing a 2.3 percent update to the national standardized amount.

This column also includes the proposed 0.8 percent update to the hospital-specific rates, which includes the proposed 2.1 percent for the proposed hospital update and proposed −1.3 documentation and coding adjustment.

Overall, hospitals will experience a 2.2 percent increase in payments primarily due to the effects of the proposed hospital update and proposed documentation and coding adjustment on the national standardized amount. Hospitals that are paid under the hospital-specific rate, namely SCHs, will see a 0.8 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate will see increases in payments less than 2.2 percent.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 3)

Column 3 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the proposed FY 2013 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2013, the MS–DRGs are calculated using the FY 2011 MedPAR data grouped to the Version 30.0 (FY 2013) MS–DRGs. The methods of calculating the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.H. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 3 indicates that changes due to the proposed MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.998546 on to the standardized amount. Due to the proposed changes to the MS–DRG GROUPER in this proposed rule, there were some shifts in payments due to changes in the relative weights with rural hospitals experiencing a 0.1 percent decrease in payments.

c. Effects of the Proposed Wage Index Changes (Column 4)

Column 4 shows the impact of proposed updated wage data with the application of the wage budget neutrality factor. Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2013 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2008 and before October 1, 2009. The estimated impact of the updated wage data and labor share on hospital payments is isolated in Column 4 by holding the other payment parameters constant in this simulation. That is, Column 4 shows the percentage change in payments when going from a model using the FY 2012 wage index, based on FY 2008 wage data, the current labor-related share and having a 100-percent occupational mix adjustment applied, to a model using the FY 2013 pre-reclassification wage index with the labor-related share, also having a 100-percent occupational mix adjustment applied, based on FY 2009 wage data (while holding other payment parameters such as use of the Version 30.0 MS–DRG GROUPER constant). The occupational mix adjustment is based on the 2010 occupational mix survey.

In addition, the column shows the proposed impact of the application of wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2013, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed wage budget neutrality factor is 1.000563, and the overall payment change is 0 percent.

Column 4 shows the impacts of updating the wage data using FY 2009 cost reports. Overall, the new wage data will lead to a 0.0 percent change for all hospitals before being combined with the wage budget neutrality adjustment shown in Column 4. Among the regions, the largest increase is in the urban New England region, which experiences a 1.0 percent increase. The largest decline from updating the wage data is seen in the rural East South Central region (−0.8 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 3.1 percent compared to FY 2012. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 3.1 percent increase in average hourly wage. Of the 3,405 hospitals with wage data for both FYs 2012 and 2013, 1,537, or 45.1 percent, experienced an average hourly wage increase of 3.1 percent or more.

The following chart compares the shifts in wage index values for hospitals for FY 2013 relative to FY 2012. Among urban hospitals, none will experience an increase of more than 5 percent and less than 10 percent and none will experience an increase of more than 10 percent. Among rural hospitals, none will experience an increase of more than 5 percent and less than 10 percent, and none will experience an increase of more than 10 percent. However, 924 rural hospitals will experience increases or decreases of less than 5 percent, while 2,481 urban hospitals will experience increases or decreases of less than 5 percent. No urban hospitals will experience decreases in their wage index values of more than 5 percent and less than 10 percent. No urban hospitals will experience decreases in their wage index values of greater than 10 percent. No rural hospitals will experience a decrease of more than 10 percent. No rural hospitals will experience decreases in their wage index values of greater than 5 percent but less than 10 percent. These figures reflect changes in the wage index which is an adjustment to either 68.8 percent or 62 percent of the labor-related share of a hospital's standardized amount, depending upon whether its wage index is greater than 1.0 or less than or equal to 1.0. Therefore, these figures illustrate a somewhat larger change in the wage index than will occur to the hospital's total payment.

The following chart shows the projected impact for urban and rural hospitals.

Percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase more than 10 percent	0	0
Increase more than 5 percent and less than 10 percent	0	0
Increase or decrease less than 5 percent	2,481	924

Percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Decrease more than 5 percent and less than 10 percent	0	0
Decrease more than 10 percent	0	0

d. Combined Effects of the Proposed MS–DRG and Wage Index Changes (Column 5)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS–DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a proposed wage budget neutrality factor of 1.000563, and a proposed recalibration budget neutrality factor of 0.998546 (which is applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two proposed budget neutrality factors is the cumulative wage and recalibration budget neutrality factor. The proposed cumulative wage and recalibration budget neutrality adjustment is 0.999108, or approximately −0.9 percent, which is applied to the national standardized amounts. Because the wage budget neutrality and the recalibration budget neutrality are calculated under different methodologies according to the statute, when the two budget neutralities are combined and applied to the standardized amount, the overall payment impact is not necessarily budget neutral. However, in this proposed rule, we are estimating that the proposed changes in the MS–DRG relative weights and updated wage data with wage and budget neutrality applied will result in a 0.0 change in payments.

We estimate that the combined impact of the proposed changes to the relative weights and MS–DRGs and the updated wage data with budget neutrality applied will result in 0.1 percent increase in payments for urban hospitals and 0.3 percent decrease in payments for rural hospitals. Urban Pacific hospitals will experience a 0.6 percent increase in payments due to increases in their wages compared to the national average, while the urban East South Central area and rural South Atlantic will experience a −70.7 decrease in payments because of below average increases in wages.

e. Effects of Proposed MGCRB Reclassifications (Column 6)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on other bases than where they are geographically located). The proposed changes in Column 6 reflect the per case payment impact of moving from this baseline to a simulation incorporating the proposed MGCRB decisions for FY 2013 which affect hospitals' wage index area assignments.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from publication of the IPPS rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for the purposes of this impact analysis, we are proposing to apply an adjustment of 0.991436 to ensure that the effects of the section 1886(d)(10) reclassifications are budget neutral (section II.A. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the proposed geographic reclassification will increase payments to rural hospitals by an average of 2.1 percent. By region, all the rural hospital categories, with the exception of the one rural Puerto Rico hospital, will experience increases in payments due to MGCRB reclassification. Rural hospitals in the East South Central region will experience a 2.9 percent increase in payments and rural hospitals in the Mountain region will experience a 0.5 percent increase in payments. Urban hospitals in New England and the Middle Atlantic will experience an increase in payments of 0.7 percent and 0.1 percent, respectively, largely due to reclassifications of hospitals in Connecticut and New Jersey.

Table 9A listed in section VI. of the Addendum to this proposed rule and available via the Internet reflects the proposed reclassifications for FY 2013.

f. Effects of the Proposed Rural and Imputed Floor, Including Application of National Budget Neutrality (Column 7)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FY 2011 IPPS/LTCH PPS final rule and this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We apply a uniform budget neutrality adjustment to the wage index. In addition, the imputed floor, which is budget neutral, was extended in FY 2012 for 2 additional years. The current imputed floor only benefits hospitals located in New Jersey. We note that we have proposed an alternative temporary methodology for the imputed floor that will have a negligible impact on budget neutrality. The impact of this proposal is discussed separately. While it is not included in the determination of budget neutrality for this proposed rule, if finalized, we intend to include it in the determination of budget neutrality in the final rule. The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. The proposed FY 2013 rural floor budget neutrality factor applied to the wage index is 0.992243, which will reduce wage indexes by −0.77 percent.

Column 7 shows the projected impact of the rural floor and imputed floor with the national rural floor budget neutrality factor applied to the wage index. The column compares the proposed post-reclassification FY 2013 wage index of providers before the rural floor and imputed floor adjustment and the proposed post-reclassification FY 2013 wage index of providers with the rural floor and imputed floor adjustment. Only urban hospitals can benefit from the rural floor provision. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) experience a decrease in payments due to the budget neutrality adjustment applied nationally to their wage index.

We project that, in aggregate, rural hospitals will experience a −0.3 percent decrease in payments as a result of the proposed application of rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in other urban areas (populations of 1 million or fewer) will experience a 0.1 percent increase in payments because those providers benefit from the rural floor. Urban hospitals in the New England region can expect a 3.1 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the application of national rural floor budget neutrality as required by the Affordable Care Act. All 60 urban providers in Massachusetts are expected to receive the rural floor wage index value, including rural floor budget neutrality, of 1.3047. During most past years, there have been no IPPS hospitals located in rural areas in Massachusetts. There was one urban IPPS hospital that was reclassified to rural Massachusetts (under section 1886(d)(8)(E) of the Act) which established the Massachusetts rural floor, but the wage index resulting from that hospital's data was not high enough for any urban hospital to benefit from the rural floor policy. However, beginning with the FY 2012 wage index, the rural floor for the State is established by the conversion of a CAH to an IPPS hospital that is geographically located in rural Massachusetts. We estimate that Massachusetts hospitals will receive

approximately a 5.5 percent increase in IPPS payments due to the application of rural floor.

Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of a Puerto Rico rural floor. Urban Puerto Rico hospitals will receive a rural floor as a result of a one IPPS hospital located in rural Puerto Rico setting a rural floor. We are applying a proposed rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.987885 or −1.2 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals.

There are 29 hospitals in New Jersey that benefit from the extension of the imputed floor and will receive the imputed floor wage index value, including rural floor budget neutrality of 1.1010, which we estimate will increase their payments by approximately $18 million. Urban Middle Atlantic hospitals will experience a −0.2 percent decrease in payments which reflects the increase in payments for New Jersey hospitals receiving the imputed floor and a decrease for all other urban hospitals in the in the Middle Atlantic region.

We note that the impact of the proposal under section III.G.2.b. of the preamble of this proposed rule to establish an alternative temporary methodology for the imputed floor is not included in the table. Based on FY 2012 wage data, we estimate that four Rhode Island hospitals will benefit from this alternative temporary methodology for the imputed floor and receive an additional $4.8 million in payments.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the proposed payment impact of the rural floor and imputed floor with budget neutrality at the State level. Column 1 of the table below displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that would receive the rural floor or imputed floor wage index for FY 2013. Column 3 displays the percentage of total payments each State would receive or contribute to fund the proposed rural floor and imputed floor with national budget neutrality. The column compares the proposed post-reclassification FY 2013 wage index of providers before the rural floor and imputed floor adjustment and the proposed post-reclassification FY 2013 wage index of providers with the rural floor and imputed floor adjustment. Column 4 displays the proposed estimated payment amount that each State would gain or lose due to the proposed application of the rural floor and imputed floor with national budget neutrality. Again, we note that the proposal under section III.G.2.b. to establish an alternative temporary methodology for the imputed floor that would benefit four hospitals located in Rhode Island is not included in this table.

FY 2013 IPPS Proposed Estimated Payments Due to Rural Floor and Imputed Floor With National Budget Neutrality

State	Number of hospitals (1)	Proposed number of hospitals receiving rural floor or imputed floor (2)	Proposed percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Proposed difference (in millions) (4)
Alabama	95	4	−0.4	−$7.1
Alaska	6	4	1.6	2.1
Arizona	56	8	−0.4	−6.1
Arkansas	45	0	−0.4	−4.5
California	308	178	1.3	113.9
Colorado	46	7	0.7	6.3
Connecticut	32	9	−0	−0.3
Delaware	5	0	−0.4	−1.8
Florida	166	8	−0.3	−23.3
Georgia	108	0	−0.4	−11.0
Hawaii	14	0	−0.3	−0.8
Idaho	14	0	−0.3	−0.7
Illinois	129	1	−0.4	−22.8
Indiana	89	0	−0.4	−10.0
Iowa	34	0	−0.4	−3.8
Kansas	55	0	−0.3	−2.6
Kentucky	65	0	−0.4	−7.4
Louisiana	97	6	−0.4	−6.2
Maine	20	0	−0.4	−2.1
Massachusetts	61	60	5.6	182.7
Michigan	96	0	−0.4	−18.6
Minnesota	51	0	−0.4	−7.3
Mississippi	64	0	−0.4	−4.7
Missouri	76	2	−0.4	−8.5
Montana	12	1	−0.2	−0.5
Nebraska	23	0	−0.3	−1.8
Nevada	24	0	−0.4	−2.9
New Hampshire	13	9	0.8	3.6
New Jersey	65	29	0.5	17.7
New Mexico	27	0	−0.3	−1.2
New York	168	0	−0.5	−41.0
North Carolina	87	0	−0.4	−13.9
North Dakota	6	0	−0.3	−0.6
Ohio	137	11	−0.3	−13.1
Oklahoma	85	0	−0.4	−4.8
Oregon	33	0	−0.4	−3.0

FY 2013 IPPS PROPOSED ESTIMATED PAYMENTS DUE TO RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Proposed number of hospitals receiving rural floor or imputed floor (2)	Proposed percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Proposed difference (in millions) (4)
Pennsylvania	154	14	−0.3	−13.8
Puerto Rico	52	13	0.2	0.2
Rhode Island	11	0	−0.5	−1.9
South Carolina	56	7	−0.3	−5.0
South Dakota	18	0	−0.2	−0.6
Tennessee	97	10	−0.3	−6.5
Texas	324	2	−0.4	−28.3
Utah	32	0	−0.3	−1.2
Vermont	6	0	−0.3	−0.6
Virginia	79	1	−0.4	−9.5
Washington	48	6	−0.4	−5.8
Washington, DC	7	0	−0.4	−1.9
West Virginia	33	2	−0.3	−2.6
Wisconsin	65	5	−0.3	−4.6
Wyoming	11	0	−0.1	−0.1

g. Effects of the Proposed Application of the Frontier State Wage Index (Column 8)

Section 10324(a) of Affordable Care Act requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in ''frontier States.'' The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, four States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 51 hospitals located in those States will receive a frontier wage index of 1.0. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 proposed rural floor value of 1.0293 is greater and, therefore, is the State's proposed minimum wage index for FY 2013. As a result, hospitals located in Nevada will not experience a change in payment as a result of this provision. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $53 million.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region will receive an increase in payments by 0.7 percent and 0.2 percent, respectively because many of the hospitals located in this region are frontier hospitals. Similarly, rural hospitals located in the Mountain region and rural hospitals in the West North Central region will experience an increase in payments by 0.8 percent and 0.2 percent, respectively.

h. Effects of the Proposed Wage Index Adjustment for Out-Migration (Column 9)

Section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. Overall, rural hospitals will experience a 0.1 percent increase in payments as a result of the proposed outmigration adjustment. Rural DSH providers with less than 100 beds will experience a 0.4 percent increase in payments. There are 213 providers that will receive the out-migration adjustment in FY 2013. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase to be approximately $18 million.

i. Effects of the Expiration of MDH Special Payment Status (Column 10)

Column 10 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision, under section 3124 of the Affordable Care Act. Hospitals that qualified to be MDHs receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a −0.1 percent decrease in payments overall. There are currenty 212 MDHs, of which 104 were estimated to be paid under the blended payment of the federal standardized amount and hospital specific rate. Because those 104 MDHs will no longer receive the blended payment and will be paid only under the Federal standardized amount in FY 2013, it is estimated that those hospitals will experience an overall decrease in payments of approximately $114 million.

MDHs were generally rural hospitals, so the expiration of th MHD program will result in an overall decrease in payments to rural hospitals of 0.9 percent. Rural New England hospitals can expect a decrease in payments of 3.5 percent because 8 out of the 23 rural New England hospitals are MDHs that will lose their special payment status under the expiration at the end of FY 2012. MDHs can expect a decrease in payments of −6.1 percent.

j. Proposed Effects of the Hospital Readmissions Reduction Program (Column 11)

Column 11 shows our estimates of proposed effects of the proposed policies for implementation of the Hospital Readmissions Reduction Program, which was established under section 3025 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions, which is based on a hospital's risk-adjusted readmission rate during a 3-year period for three applicable conditions: Acute Myocardial Infarction, Heart Failure, and Pneumonia. This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in statute as 0.99 (or a 1-

percent reduction) for FY 2013. A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as proposed in section IV.A. of the preamble of this proposed rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this proposed rule, we estimate that 2,210 hospitals will have their base operating DRG payments reduced by the readmissions adjustment, resulting in a 0.3 percent decrease in payments to hospitals overall.

Urban hospitals in the Middle Atlantic, rural hospitals in the West South Central region, rural DSH hospitals with more than 100 beds, and hospitals with Medicare utilization of over 65 percent are estimated to experience the highest decreases of 0.5 percent among the different hospital categories. Urban and rural hospitals in the Mountain Region and Rural Pacific hospitals are expected to experience the smallest decreases of 0.1 percent in payments. Puerto Rico hospitals are estimated to show a 0 percent change in payments because they are exempt from the provision.

k. Effects of All FY 2013 Proposed Changes (Column 12)

Column 12 shows our estimate of the changes in payments per discharge from FY 2012 and FY 2013, resulting from all proposed changes reflected in this proposed rule for FY 2013. It includes combined effects of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 0.9 percent for FY 2013 relative to FY 2012. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2013 documentation and coding adjustment of 0.2 percent on the national standardized amount (the proposed −2.7 documentation and coding adjustment and 2.9 percent adjustment to restore the one-time recoupment adjustment made to national standardized amount) and the proposed −1.3 percent documentation and coding adjustment on the hospital-specific rates. In addition, this column includes the proposed annual hospital update of 2.1 percent to the national standardized amount. This proposed annual hospital update includes the 3.0 percent proposed market basket update, the proposed reduction of 0.8 percentage point for the proposed multifactor productivity adjustment, and the 0.1 percentage point reduction under section 3401 of the Affordable Care Act. As described in Column 2, the proposed annual hospital update, combined with the documentation and coding adjustment, results in a 2.2 percent increase in payments in FY 2013 relative to FY 2012. In addition, Column 8 describes an estimated 0.1 percent increase in payments due to the proposed frontier State wage index. Column 10 describes the estimated 0.1 percent decrease in payments due to the expiration of the MDH status under section 3124 of the Affordable Care Act. Column 11 shows the estimated 0.3 percent decrease in payments due to the establishment of the Hospital Readmissions Reduction Program, which reduces a hospital's base operating DRG payments by a readmission adjustment factor based on a hospital's performance on readmissions for specified conditions. In addition, although not shown in the impacts table, payments are estimated to decrease by 0.1 due to the expiration of section 508 reclassifications that had been extended for 6 months of FY 2012 under section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96). Section 508 was not a budget-neutral provision. The impact of moving from our proposed estimate of FY 2012 outlier payments, 6.0 percent, to the estimate of FY 2013 outlier payments, 5.1 percent, results in a decrease of 0.9 percent in FY 2013 payments relative to FY 2012. There might also be interactive effects among the various factors comprising the payment system that we are not able to isolate. For these reasons, the values in Column 12 may not equal the sum of the percentage changes described above.

The overall change in payments per discharge for hospitals paid under the IPPS in FY 2013 is estimated to increase by 0.9 percent. The payment increase among the hospital categories are largely attributed to the proposed updates to the rate including the hospital update. Hospitals in urban areas will experience an estimated 1.1 percent increase in payments per discharge in FY 2013 compared to FY 2012. Hospital payments per discharge in rural areas are estimated to increase by 0.5 percent in FY 2013 as compared to FY 2012 due to the expiration of MDH status.

Among urban census divisions, the Urban New England hospitals will experience a −0.4 percent change in payments because many of the urban providers in this region had benefited from section 508 reclassifications in FY 2012 that will expire for FY 2013. Urban hospitals in the Pacific will see the largest payment increases (2.4 percent) because the hospitals are benefitting from the rural floors in their States.

Among the rural regions, the providers in the New England Region will experience the decreases in payments of −2.1 percent, due to the expiration of MDH status. Rural hospitals in the Pacific Region are estimated to experience a 0.0 percent change because the rural providers in this region benefit from higher than average wage data and MGCRB reclassification, which offsets decreases due to the rural floor and the expiration of MDH status.

Among special categories of hospitals, former MDHs will receive an estimated payment decrease of −7 percent due to the expiration of the MDH status. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs are estimated to experience a decrease in payments by 0.4 percent due to decreases in their wage data and the implementation of the Hospital Readmissions Reduction Program.

Proposed rural hospitals reclassified for FY 2013 are anticipated to receive a 0.5 percent payment increase. Rural hospitals that are not reclassifying are estimated to receive a payment decrease of −1.8 percent due to lower wage data, the proposed application of rural floor budget neutrality and expiration of MDH status. Urban reclassified hospitals will experience the average payment increase at 1.1 percent due to the benefits under MGCRB reclassification and the proposed rural floor. Urban nonreclassified hospitals will experience a payment increase of 1.0 percent.

Cardiac hospitals are expected to experience a payment increase 2.7 percent in FY 2013 relative to FY 2012 primarily due to benefits to the changes in the relative weights.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2013 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the proposed estimated average payments per discharge for FY 2012 with the proposed average payments per discharge for FY 2013, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 12 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2013 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of hospitals (1)	Proposed average FY 2012 payment per discharge (2)	Proposed average FY 2013 payment per discharge (3)	All proposed FY 2013 changes (4)
All hospitals	3,405	10,447	10,539	0.9
By Geographic Location:				
Urban hospitals	2,485	10,859	10,971	1
Large urban areas (populations over 1 million)	1,365	11,469	11,602	1.2

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2013 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)—Continued

	Number of hospitals (1)	Proposed average FY 2012 payment per discharge (2)	Proposed average FY 2013 payment per discharge (3)	All proposed FY 2013 changes (4)
Other urban areas (populations of 1 million or fewer)	1,120	10,110	10,198	0.9
Rural hospitals	920	7,790	7,752	−0.5
Bed Size (Urban):				
0–99 beds	627	8,277	8,361	1
100–199 beds	773	9,126	9,227	1.1
200–299 beds	448	9,882	9,996	1.2
300–499 beds	432	11,091	11,219	1.2
500 or more beds	205	13,475	13,581	0.8
Bed Size (Rural):				
0–49 beds	317	6,222	6,106	−1.9
50–99 beds	346	7,270	7,093	−2.4
100–149 beds	152	7,529	7,551	0.3
150–199 beds	58	8,487	8,537	0.6
200 or more beds	47	9,615	9,725	1.1
Urban by Region:				
New England	120	11,860	11,818	−0.4
Middle Atlantic	318	11,946	12,009	0.5
South Atlantic	377	9,984	10,060	0.8
East North Central	396	10,147	10,266	1.2
East South Central	151	9,601	9,651	0.5
West North Central	165	10,544	10,736	1.8
West South Central	370	10,216	10,333	1.1
Mountain	157	11,013	11,145	1.2
Pacific	380	13,609	13,942	2.4
Puerto Rico	51	5,369	5,458	1.7
Rural by Region:				
New England	23	10,441	10,219	−2.1
Middle Atlantic	69	8,291	8,246	−0.5
South Atlantic	164	7,526	7,503	−0.3
East North Central	120	8,014	7,942	−0.9
East South Central	170	7,167	7,161	−0.1
West North Central	98	8,248	8,193	−0.7
West South Central	181	6,868	6,830	−0.5
Mountain	65	8,603	8,658	0.6
Pacific	29	10,599	10,594	0
Puerto Rico		2,104	2,182	3.7
By Payment Classification:				
Urban hospitals	2,500	10,838	10,952	1
Large urban areas (populations over 1 million)	1,375	11,449	11,577	1.1
Other urban areas (populations of 1 million or fewer)	1,125	10,082	10,178	1
Rural areas	905	7,991	7,947	−0.5
Teaching Status:				
Non-teaching	2,376	8,721	8,784	0.7
Fewer than 100 Residents	789	10,259	10,374	1.1
100 or more Residents	240	15,474	15,600	0.8
Urban DSH:				
Non-DSH	758	9,075	9,121	0.5
100 or more beds	1,523	11,370	11,494	1.1
Less than 100 beds	327	7,582	7,671	1.2
Rural DSH:				
SCH	269	7,827	7,764	−0.8
RRC	210	8,855	8,912	0.6
100 or more beds	32	6,913	6,889	−0.3
Less than 100 beds	286	6,158	5,995	−2.6
Urban teaching and DSH:				
Both teaching and DSH	815	12,443	12,570	1
Teaching and no DSH	147	10,014	10,087	0.7
No teaching and DSH	1,035	9,259	9,375	1.3
No teaching and no DSH	503	8,643	8,717	0.9
Rural Hospital Types:				
RRC	199	8,848	8,924	0.9
SCH	340	8,281	8,251	−0.4
Former MDH	195	6,423	5,975	−7
SCH and RRC	101	9,678	9,717	0.4
Former MDH and RRC	17	8,678	7,396	−14.8
Type of Ownership:				
Voluntary	1,970	10,592	10,680	0.8

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2013 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)—Continued

	Number of hospitals (1)	Proposed average FY 2012 payment per discharge (2)	Proposed average FY 2013 payment per discharge (3)	All proposed FY 2013 changes (4)
Proprietary	866	9,262	9,365	1.1
Government	560	11,108	11,210	0.9
Medicare Utilization as a Percent of Inpatient Days:				
0–25	377	14,766	15,027	1.8
25–50	1,834	10,949	11,056	1
50–65	968	8,543	8,573	0.4
Over 65	168	7,926	7,889	−0.5
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
Proposed FY 2013 Reclassifications:				
All Reclassified Hospitals FY 2013	755	10,018	10,106	0.9
All Non-Reclassified Hospitals FY 2013	2,650	10,585	10,678	0.9
Urban Reclassified Hospitals FY 2013:	420	10,811	10,931	1.1
Urban Non-reclassified Hospitals FY 2013	2,025	10,882	10,996	1
Rural Reclassified Hospitals FY 2013	335	8,349	8,370	0.2
Rural Nonreclassified Hospitals FY 2013:	524	6,950	6,825	−1.8
All Section 401 Reclassified Hospitals:	46	9,905	9,760	−1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	7,383	7,202	−2.4
Specialty Hospitals				
Cardiac Hospitals	18	10,898	11,194	2.7

H. Effects of Other Policy Changes

In addition to those proposed policy changes discussed above that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed below.

1. Effects of Proposed Policy on HACs, Including Infections

In section II.F. of the preamble of this proposed rule, we discuss our implementation of section 1886(d)(4)(D) of the Act, which requires the Secretary to identify conditions that are: (1) High cost, high volume, or both; (2) result in the assignment of a case to an MS–DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission, unless, based on data and clinical judgment, it cannot be determined at the time of admission whether a condition is present. That is, the case will be paid as though the secondary diagnosis were not present. However, the statute also requires the Secretary to continue counting the condition as a secondary diagnosis that results in a higher IPPS payment when doing the budget neutrality calculations for MS–DRG reclassifications and recalibration. Therefore, we will perform our budget neutrality calculations as though the payment provision did not apply, but Medicare will make a lower payment to the hospital for the specific case that includes the secondary diagnosis. Thus, the provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the selected conditions are the only secondary diagnosis or diagnoses present on the claim that will lead to higher payment. Medicare beneficiaries will generally have multiple secondary diagnoses during a hospital stay, such that beneficiaries having one MCC or CC will frequently have additional conditions that also will generate higher payment. Only a small percentage of the cases will have only one secondary diagnosis that would lead to a higher payment. Therefore, if at least one nonselected secondary diagnosis that leads to higher payment is on the claim, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case. In addition, as discussed in section II.F.3. of the preamble of this proposed rule, it is possible to have two severity levels where the HAC does not affect the MS–DRG assignment or for an MS–DRG not to have severity levels. In either of these circumstances, the case will continue to be assigned to the higher paying MS–DRG and there will be no Medicare savings from that case.

In section II.F. of the preamble of this proposed rule, we are proposing to add two additional HACs for FY 2013: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Iatrogenic Pneumothorax with Venous Catheterization. Similar to the current HACs, only a very small number of discharges would have only one secondary diagnosis that would lead to a higher payment. Therefore, there will likely be very few discharges where the MS–DRG is reassigned for these proposed conditions and this would result in a minimal payment impact.

The HAC payment provision went into effect on October 1, 2008. Our savings estimates for the next 5 fiscal years are shown below:

Year	Savings (in millions)
FY 2013	$24
FY 2014	26
FY 2015	28
FY 2016	30
FY 2017	33

2. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this proposed rule, we discuss the five applications for add-on payments for new medical services and technologies for FY 2013, as well as the status of the new technology that was approved to receive new technology add-on payments in FY 2012. As explained in that section, add-on payments for new technology under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.4. of the preamble of this proposed rule, we have yet to determine whether any of the five applications we received for consideration for new technology add-on payments for FY 2013 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these five applications for any potential new technology add-on payments for FY 2013. We note that if any of the five applications are found to be eligible for new technology add-on payments for FY 2013 in the FY 2013 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2013 in that final rule. In the preamble to this proposed rule, we are proposing not to

continue making new technology add-on payments for the AutoLITT™ in FY 2013. Therefore, we are not providing an impact analysis for the AutoLITT™ in this proposed rule.

3. Effects of Proposed Policy Changes Relating to SCHs

In section IV.B.2. of the preamble of this proposed rule, we discuss our proposal to clarify the regulations related to the termination of a hospital's status as an SCH. We are proposing to add a provision to the regulations to clarify that if CMS determines that the hospital was incorrectly classified as an SCH, SCH status would be cancelled retroactively, consistent with the provisions at 42 CFR 405.1885. We also are proposing that if a hospital that was incorrectly designated as an SCH notifies CMS of that error, the SCH classification status will be terminated effective with the date of the notice to CMS. We believe it would be difficult to quantify the payment impact of these proposed clarifications because we cannot estimate the number of SCHs that would be affected by these proposals. However, we believe any impact would be insignificant because the proposal only affects hospitals that were incorrectly classified as SCHs. We are soliciting public comments on these issues.

In section IV.B.3. of the preamble of this proposed rule, we discuss our proposal to add a provision to the regulations to allow hospitals that are currently classified as MDHs to apply for classification as SCHs upon the expiration of the MDH program on September 30, 2012. We are proposing that, for any MDH that applies for SCH classification at least 30 days prior to the expiration of the MDH program and requests that SCH classification status be effective with the expiration of the MDH program, and the hospital is approved for SCH status, the effective for SCH status would be the day following the expiration of the MDH program. We believe it would be difficult to quantify the payment impact of this proposal because we cannot estimate the number of MDHs that would be applying for SCH status.

4. Effects of the Proposed Payment Adjustment for Low-Volume Hospitals for FY 2013

In section IV.D. of the preamble to this proposed rule, we discuss the provisions of the Affordable Care Act that expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition for FYs 2011 and 2012. In accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, effective for FY 2013 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospitals and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year.

Based on FY 2011 claims data (December 2011 update of the MedPAR file), we estimate that approximately 600 hospitals in our database qualified as a low-volume hospital for FY 2012, but will no longer meet the mileage and discharges criteria to qualify as a low-volume hospital under section 1886(d)(12) of the Act for FY 2013. Because we estimate that these hospitals will no longer qualify for the low-volume hospital adjustment in FY 2013 (due to the statutory change in the qualifying criteria), we project that these hospitals will experience a decrease in payments of approximately $300 million in FY 2013 as compared to the payments that they would have otherwise received in FY 2013 in absence of the statutory change in the low-volume hospital qualifying criteria.

5. Effects of Proposed Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)

In section IV.F. of the preamble of this proposed rule, we discuss our proposal to include ancillary labor and delivery beds in the available bed count used to determine the DSH payment adjustment and the IME payment adjustment. The impact of the proposed changes to the DSH payment adjustment should be negligible, as the DSH payment adjustment is determined mainly by the demographic composition of an individual hospital's patient population, and not its overall bed count. However, we note that some hospitals' bed counts do not meet the minimum threshold required to qualify for the DSH payment adjustment. For these hospitals that do not meet the minimum bed count required to qualify for the DSH payment adjustment, an increase in the number of available beds could now allow them to qualify for the DSH payment adjustment. For purposes of the IME payment adjustment, an increase in a hospital's number of available beds would result in a decrease in the resident-to-bed ratio. The inclusion of bed days associated with labor and delivery patients in the available bed count for IME would increase the available beds, decrease the resident-to-bed ratio, and, consequently, decrease IME payments to teaching hospitals, depending on the number of these hospitals' labor and delivery beds. Based on labor and delivery patient days currently reported in the Medicare hospital cost report database, we estimate that the inclusion of labor and delivery beds in the available bed day count would decrease IME payments by $170 million in FY 2013.

6. Effects of the Proposed Policy Changes Relating to GME and IME

a. Effects of Clarification and Proposal Regarding Timely Filing Requirements Under Fee-for-Service Medicare

In section IV.E.2. of the preamble of this proposed rule, we discuss a clarification related to the time limits for filing claims for Medicare Advantage patients under fee-for-service Medicare for IME, direct GME, and nursing and allied health education payment purposes. This clarification is intended to make clear to hospitals that they must follow the regulations governing the time limits for filing claims at § 424.44 in order to receive IME, and/or direct GME, and/or nursing or allied health education program payments associated with Medicare Advantage enrollees. Because we are not proposing to make any policy changes (but rather clarifying the timely filing requirements), there is no financial impact for this clarification.

In section IV.E.2. of the preamble of this proposed rule, we also are proposing to adopt a policy under which hospitals that are required to submit no pay bills for the purpose of calculating the DPP that is used in determining the DSH payment adjustment must do so within the time limits for filing claims at § 424.44. We do not anticipate that this proposal would have any impact, as providers are already submitting no pay bills for purposes of the DPP.

b. Effects of Proposed Policy Changes Relating to New Teaching Hospitals: New Program Growth From 3 Years to 5 Years

In section IV.I.2. of the preamble of this proposed rule, we discuss our proposal to extend the period a new teaching hospital has to establish its caps for direct GME and IME payment purposes from 3 years to 5 years. We are proposing to revise the regulations to state that if a new teaching hospital participates in training residents in a new program for the first time on or after October 1, 2012, that new teaching hospital's caps will be based on the product of the highest number of FTE residents training in any program year during the fifth academic year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The cap would be applied beginning with the sixth academic year of the first new program. We believe this expansion of the cap-building period from 3 years to 5 years would make our policies for the establishment of a hospital's cap more compatible with current accreditation requirements that hospitals must meet to establish new residency training programs. We estimate that this proposal would cost approximately $175 million over the next 10 years. However, because this proposal to change the cap growth period from 3 years to 5 years would only affect new programs begun on or after October 1, 2012, we estimate that no cost would be incurred until FY 2016. This estimate assumes that there could be 20 new teaching hospitals each year.

c. Effects of Proposed Changes Relating to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 5503 of the Affordable Care Act

In section IV.I.3. of the preamble of this proposed rule, we discuss our proposals related to the 5-year period following implementation of reductions and increases to hospitals' FTE resident caps for GME payment purposes under section 5503 of the Affordable Care Act. Section 5503 of the Affordable Care Act amended the Medicare statute by adding a new section 1886(h)(8) of

the Act, which provides for reductions in the statutory FTE resident caps for direct GME and IME under Medicare for certain hospitals, and authorizes a ''redistribution'' to certain hospitals of the estimated number of FTE resident slots resulting from the reductions. The amendments made by section 5503 also specifies that a hospital that receives an increase in its cap shall ensure, during the 5-year period beginning on the date of such increase (July 1, 2011), that certain requirements, referred to as the primary care average and 75-percent threshold, are met in order to retain those slots. Otherwise, the Medicare statute authorizes the Secretary to reduce the FTE caps of the hospital by the same number of FTE residents by which the hospital's FTE caps were increased if the hospital fails to meet either of those requirements.

Because a statutorily directed criteria for consideration in awarding slots under section 5503 included the requirement that hospitals applying for slots demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, and we relied on that information in awarding slots, we believe it is reasonable and authorized under section 1886(h)(8)(B)(ii) of the Act to expect that hospitals that received slots under section 5503 begin to use their slots by Year 3 of the 5-year period in order to give full effect to the requirements under section 1886(h)(8)(B)(ii) of the Act. Therefore, we are proposing that a hospital that received section 5503 slots must fill at least half of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes: The first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period and/or in its third 12-month cost reporting period of the 5-year period, or lose its section 5503 slots. We also are proposing that the hospital must fill all of the slots it received by its final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016, or lose all of its section 5503 slots after June 30, 2016.

We believe the impact of these proposals regarding the timing of the use of these section 5503 slots is budget neutral. We believe that hospitals will take the steps necessary to comply with the section 5503 requirements to ensure, to the best of their ability, that they will not lose their section 5503 slots. We believe that section 5503 slots are valuable enough to a hospital that it is worthwhile for the hospital to comply with the proposed regulations (that is, to fill at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period and/or in its third 12-month cost reporting period of the 5-year period, and also fill all of the slots it received by its final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016), because not doing so would mean the loss of all of its section 5503 slots after Year 5 ends. Therefore, we anticipate that, as a result of these proposals, the hospitals that previously might not have made an effort to fill their section 5503 slots in a timely manner will now do so, and, assuming they continue to meet the primary care average and 75-percent threshold requirements, those hospitals would be allowed to keep their section 5503 slots. Thus, there would be neither an additional cost due to these proposals nor savings related to these proposals.

d. Preservation of Resident Cap Positions From Closed Hospitals (Section 5506 of the Affordable Care Act)

In section IV.I.4. of the preamble of this proposed rule, we discuss our proposals and clarifications of existing policy related to section 5506 of the Affordable Care Act. Section 5506 amended the Medicare statute to add a provision that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the total number of FTE resident cap slots distributed is not to exceed the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively. The regulations and application process regarding section 5506 were implemented in the November 24, 2010 **Federal Register** (75 FR 72212). The provisions included in the preamble of this proposed rule are generally administrative in nature, related to the rules regarding the application of section 5506, minor proposed changes or clarifications to the ranking criteria on the applications, and minor proposed changes or clarifications regarding the effective dates of slots awarded under section 5506. Therefore, there is no financial impact for these section 5506 provisions.

7. Effects of Proposed Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

In section IV.J. of the preamble of this proposed rule, we discuss our proposal to amend two existing regulations to conform these regulations to the final policy we adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51597) with regard to pension costs for Medicare cost-finding purposes. Because we are proposing to make only conforming changes to the regulations and not further modifying the policy we finalized, there is no impact on hospitals for these proposed changes for FY 2013.

8. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.K. of the preamble of this proposed rule, we discuss our implementation of section 410A of Public Law 108–173, as amended, which requires the Secretary to conduct a demonstration that would modify reimbursement for inpatient services for up to 30 rural community hospitals. Section 410A(c)(2) requires that ''[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.'' As discussed in section IV.K. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 8 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we are proposing to adjust the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are proposing to apply budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that ''aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented'' but does not identify the range across which aggregate payments must be held equal.

We are proposing to adjust the national IPPS rates according to the methodology set forth elsewhere in this proposed rule. In this proposed rule, the proposed adjustment to the national IPPS rates to account for estimated demonstration cost for FY 2013 for the 7 ''pre-expansion'' participating hospitals that are currently participating in the demonstration and the 16 additional hospitals participating as a result of the expansion of the demonstration under the Affordable Care Act is $35,077,708. In addition, in this FY 2013 proposed rule, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable budget year (FY 2007, 2008, 2009, or 2010) are available prior to the FY 2013 IPPS/LTCH PPS final rule, we would include in the budget neutrality offset amount any additional amount by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. The estimated amount of $35,077,708 that we are proposing in this FY 2013 proposed rule does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration for FYs 2007 through 2010 and the amounts that were offset by the budget neutrality adjustment for these years because the specific numeric value associated with this component of the adjustment to the national IPPS rates cannot be known at this time. This is because the large majority of settled cost reports beginning in FYs 2007 through 2010 for the hospitals participating during in the demonstration during those years also are not available at this time.

9. Effects of Proposed Change in Effective Date for Policies Relating to Hospital Services Furnished Under Arrangements

In section IV.L. of the preamble of this proposed rule, we discuss that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we limited the circumstances under which a hospital may furnish services to Medicare beneficiaries ''under arrangements.'' Under the revised policy, ''routine services'' (that is, bed, board,

and nursing and other related services) must be provided in the hospital in which the patient is a registered inpatient in order for the services to be considered as being provided by the hospital. Routine services furnished to Medicare beneficiaries as inpatients of the hospital are considered services furnished by the hospital. Only diagnostic and therapeutic services (that is, ancillary services) may be provided under arrangements outside the hospital. We have become aware that a number of affected hospitals need additional time to restructure existing arrangements and establish necessary operational protocols to comply with this requirement. Therefore, in this proposed rule, we are proposing to postpone the effective date of the revised policy change from services provided on or after October 1, 2011, to cost reporting periods beginning in FY 2014. We have determined that the impact of this proposed effective date change would be negligible.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2011 update of the FY 2011 MedPAR file and the December 2011 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2011 update of the most recently available hospital cost report data (FYs 2009 and 2010) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described below. In addition, as discussed in section V.C.2. of the preamble to this proposed rule, we are proposing to make a −0.8 percent documentation and coding adjustment to the national capital rate for FY 2013 in addition to the −0.6 percent adjustment established for FY 2008, the −0.9 percent adjustment for FY 2009, the −2.9 percent adjustment for FY 2011, and the −1.0 percent adjustment for FY 2012. This results in a proposed cumulative adjustment factor of 0.9404 that we applied in determining the proposed FY 2013 national capital rate to account for improvements in documentation and coding that do not reflect real changes in case mix under the MS–DRGs. We note that we applied a −2.6 percent documentation and coding adjustment to the Puerto Rico-specific capital rate in FY 2011, which reflects the entire amount of our current estimate of the effects of documentation and coding for FYs 2008 and 2009 that do not reflect real changes in case-mix under the MS–DRGs. (We currently estimate that there was no additional effect of documentation and coding from the adoption of the Ms-DRGs in FY 2010 for hospitals located in Puerto Rico.) Therefore, as we did for FY 2012, we are not proposing to adjust the Puerto Rico-specific capital rate in FY 2013 to account for changes in documentation and coding.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2011 update of the FY 2011 MedPAR file, we simulated payments under the capital IPPS for FY 2012 and FY 2013 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (Indian Health Service hospitals and hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating capital IPPS payments in FY 2013 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may also receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index would increase by 0.5 percent in both FYs 2012 and 2013.
- We estimate that the Medicare discharges would be approximately 12.8 million in FY 2012 and 13.3 million in FY 2013.
- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this proposed rule, the proposed update is 1.3 percent for FY 2013.
- In addition to the proposed FY 2013 update factor, the proposed FY 2013 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality factor of 1.0002, and a proposed outlier adjustment factor of 0.9400.
- For FY 2013, as discussed above and in section V.C.2. of the preamble to this proposed rule, we are proposing to apply a cumulative adjustment of 0.9404 in determining the proposed FY 2013 national capital rate for changes in documentation and coding that are expected to increase case-mix under the MS–DRGs but do not reflect real case-mix change. This proposed cumulative adjustment of 0.9404 reflects the additional −0.8 percent adjustment in FY 2013 for the effects of documentation and coding in FY 2010 (and is in addition to the adjustments previously made for the effects in FYs 2008 and 2009).

2. Results

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2013 on total capital payments per case, using a universe of 3,405 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2011 update of the FY 2011 MedPAR file, the December 2011 update to the PSF, and the most recent cost report data from the December 2011 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2012 and estimated total payments per case for FY 2013 based on the proposed FY 2013 payment policies. Column 2 shows estimates of payments per case under our model for FY 2012. Column 3 shows estimates of payments per case under our model for FY 2013. Column 4 shows the proposed total percentage change in payments from FY 2012 to FY 2013. The proposed change represented in Column 4 includes the 1.3 percent update to the proposed capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2013 are expected to decrease as compared to capital payments per case in FY 2012. However, the proposed capital rate for FY 2013 would increase approximately 0.7 percent as compared to the FY 2012 capital Federal rate. The proposed changes to the GAFs are expected to result, on average, in a slight decrease in capital payments for most regions with the certain exceptions. The regional variations in the proposed estimated change in capital payments are consistent with the proposed changes in payments due to changes in the wage index (and policies affecting the wage index) shown in Table I in section I of this Appendix.

We also are estimating a slight decrease in outlier payments in FY 2013 as compared to FY 2012. This is primarily because of the proposed increase to the outlier fixed-loss amount (discussed in section II.A.4.f. of the Addendum to this proposed rule). In addition, this estimated decrease in outlier payments is based on the FY 2011 claims from the December 2011 update of the MedPAR file, we are currently estimating that FY 2012 capital outlier payments are more than the projected 6.18 percent that we used to determine the outlier offset that we applied in determining the FY 2012 capital Federal rate.

The net impact of these proposed changes, as discussed above, is an estimated −0.2 percent change in capital payments per discharge from FY 2012 to FY 2013 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, all hospitals are expected to experience a decrease in capital IPPS payments per case in FY 2013 as compared to FY 2012. These decreases are primarily due to proposed changes in the GAFs (primarily resulting from policies affecting

the wage index)), and the estimated decrease in capital outlier payments. Capital IPPS payments per case for large urban hospitals are estimated to decrease 0.1 percent, while other urban hospitals are expected to experience a 0.4 percent decrease. Rural hospitals, on average, are not expected to experience any change in capital payments per discharge from FY 2012 to FY 2013.

The comparisons by region show that most urban regions, except for the Pacific region and Puerto Rico, will experience, on average, decreases in capital IPPS payments. The estimated decrease in capital payments per discharge from FY 2012 to FY 2013 in urban areas ranges from a 0.1 percent decrease for the East North Central urban region to a 1.0 percent decrease for the New England urban region. The two exceptions to decreases in capital payments per case are the Pacific urban region and the Puerto Rico urban region, which are expected to experience a 1.1 percent and 0.5 percent increase, respectively. As we indicated in the FY 2012 IPPS/LTCH PPS final rule, the GAFs for Puerto Rico result in a positive effect in estimated capital IPPS payment because of the application of a Puerto Rico rural floor. FY 2012 was the first year an IPPS hospital was located in rural Puerto Rico, therefore, setting a rural floor. The GAFs are also having a positive effect on capital IPPS payments per discharge in the Pacific urban region, primarily due to proposed changes in the wage index for hospitals located in that area as discussed in section I of this Appendix.

For rural regions, the estimated change in capital payments per discharge from FY 2012 to FY 2013 ranges from a 1.6 percent decrease for the Pacific rural region to a 0.7 percent increase for the Middle Atlantic rural region. The East South Central and Mountain rural regions are not expected to experience any change in their capital payments per discharge from FY 2012 to FY 2013. The Puerto Rico rural region is estimated to experience a 3.3 percent increase in capital payments per discharge in FY 2013 compared to FY 2012.

Hospitals of all type of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are estimated to experience a 0.2 percent decrease in capital payments per case from FY 2012 to FY 2013.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2013. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified for FY 2013, we show the average capital payments per case for reclassified hospitals for FY 2013. Only urban reclassified hospitals are expected to experience an increase in capital payments, 0.1 percent, in FY 2013 as compared to FY 2012. Urban non-reclassified hospitals are estimated to experience a decrease of 0.3 percent. Rural reclassified hospitals are estimated to experience no change in capital payments per discharge from FY 2012 to FY 2013, while rural nonreclassified hospitals are estimated to have a 0.1 percent decrease in capital payments per case. Similarly, other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience a decrease of 0.1 percent in capital payments from FY 2012 to FY 2013.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2012 payments compared to proposed FY 2013 payments]

	Number of hospitals	Average FY 2012 payments/case	Proposed average FY 2013 payments/case	Change
By Geographic Location:				
All hospitals	3,405	799	797	−0.2
Large urban areas (populations over 1 million)	1,365	880	880	−0.1
Other urban areas (populations of 1 million of fewer)	1,120	784	781	−0.4
Rural areas	920	552	552	0.0
Urban hospitals	2,485	837	835	−0.2
0–99 beds	627	670	667	−0.4
100–199 beds	773	722	720	−0.2
200–299 beds	448	769	770	0.1
300–499 beds	432	848	848	0.0
500 or more beds	205	1,016	1,010	−0.6
Rural hospitals	920	552	552	0.0
0–49 beds	317	438	438	0.1
50–99 beds	346	505	506	0.0
100–149 beds	152	545	544	−0.1
150–199 beds	58	619	617	−0.3
200 or more beds	47	672	673	0.2
By Region:				
Urban by Region	2,485	837	835	−0.2
New England	120	907	898	−1.0
Middle Atlantic	318	886	884	−0.2
South Atlantic	377	781	776	−0.6
East North Central	396	804	804	−0.1
East South Central	151	730	725	−0.7
West North Central	165	836	841	0.7
West South Central	370	796	791	−0.6
Mountain	157	868	864	−0.4
Pacific	380	1,016	1,026	1.1
Puerto Rico	51	384	386	0.5
Rural by Region	920	552	552	0.0
New England	23	744	743	−0.1
Middle Atlantic	69	569	573	0.7
South Atlantic	164	541	540	−0.2
East North Central	120	576	577	0.1
East South Central	170	507	507	0.0
West North Central	98	585	582	−0.4
West South Central	181	491	491	0.1
Mountain	65	580	580	0.0
Pacific	29	723	712	−1.6
Puerto Rico	1	150	155	3.3

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2012 payments compared to proposed FY 2013 payments]

	Number of hospitals	Average FY 2012 payments/case	Proposed average FY 2013 payments/case	Change
By Payment Classification:				
All hospitals	3,405	799	797	−0.2
Large urban areas (populations over 1 million)	1,375	879	879	−0.1
Other urban areas (populations of 1 million of fewer)	1,125	783	780	−0.3
Rural areas	905	563	561	−0.2
Teaching Status:				
Non-teaching	2,376	680	679	−0.2
Fewer than 100 Residents	789	790	790	0.0
100 or more Residents	240	1,137	1,133	−0.4
Urban DSH:				
100 or more beds	1,523	863	861	−0.1
Less than 100 beds	327	583	585	0.2
Rural DSH:				
Sole Community (SCH/EACH)	269	519	517	−0.4
Referral Center (RRC/EACH)	210	624	623	−0.3
Other Rural:				
100 or more beds	32	506	504	−0.5
Less than 100 beds	286	446	447	0.2
Urban teaching and DSH:				
Both teaching and DSH	815	933	932	−0.2
Teaching and no DSH	147	812	810	−0.3
No teaching and DSH	1,035	720	720	0.0
No teaching and no DSH	503	741	736	−0.7
Rural Hospital Types:				
Non special status hospitals	2,391	841	839	−0.2
RRC/EACH	61	733	736	0.4
SCH/EACH	34	722	724	0.2
SCH, RRC and EACH	16	769	764	−0.6
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY 2013 Reclassifications:				
All Urban Reclassified	420	833	834	0.1
All Urban Non-Reclassified	2,025	840	838	−0.3
All Rural Reclassified	335	596	596	0.0
All Rural Non-Reclassified	524	482	481	−0.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	55	550	550	−0.1
Type of Ownership:				
Voluntary	1,970	813	812	−0.2
Proprietary	866	718	717	−0.2
Government	560	817	816	−0.2
Medicare Utilization as a Percent of Inpatient Days:				
0–25	377	1,044	1,047	0.3
25–50	1,834	839	837	−0.3
50–65	968	666	665	−0.1
Over 65	168	611	611	0.1

J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2013. In the preamble, we specify the statutory authority for the proposed provisions that are presented, identify those proposed policies, and present rationales for our proposed decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, our database of 427 LTCHs includes the data for 82 nonprofit (voluntary ownership control) LTCHs and 322 proprietary LTCHs. Of the remaining 23 LTCHs, 14 LTCHs are government-owned and operated and the ownership type of the other 9 LTCHs is unknown. In the impact analysis, we used the proposed rate, factors, and policies presented in this proposed rule, including the proposed 2.1 percent annual update, which is based on the full increase of the proposed LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act, the proposed one-time prospective adjustment of 0.98734 (approximately −1.3 percent), which would not apply to payments for discharges occurring on or before December 28, 2012 (consistent with the statute), the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, the expiration of the statutory delay in the application of very short-stay outlier policy at § 412.529(c)(3), effective for discharges occurring on or after December 29, 2012 (that is, the option for certain short-stay outlier cases to be paid under the ''blended payment'' will be replaced with the ''IPPS comparable per diem amount'' as discussed in section VII.E.3. of the preamble of this proposed rule), and the best available claims and CCR data to estimate the proposed change in payments for FY 2013.

The standard Federal rate for FY 2012 was $40,222.05. For FY 2013, we are proposing to establish a standard Federal rate of $40,507.48 that reflects the proposed 2.1 percent annual update to the standard

Federal rate, and the proposed area wage budget neutrality factor of 0.99903, which ensures that the proposed changes in the wage indexes and labor-related share do not influence aggregate payments. Furthermore, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately −1.3 percent) would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed adjustment and, instead, would be paid based on a standard Federal rate of $41,026.88.

Based on the best available data for the 427 LTCHs in our database, we estimate that the proposed update to the standard Federal rate for FY 2013 (discussed in section V.A.2. of the Addendum to this proposed rule) and the proposed changes to the area wage adjustment for FY 2013 (discussed in section V.B. of the Addendum to this proposed rule), in addition to an estimated increase in HCO payments and an estimated decrease in SSO payments, would result in an increase in estimated payments from FY 2012 of approximately $100 million. Based on the 427 LTCHs in our database, we estimate that the FY 2013 LTCH PPS payments would be approximately $5.282 billion, as compared to estimated FY 2012 LTCH PPS payments of approximately $5.181 billion. Because the combined distributional effects and estimated changes to the Medicare program payments are over approximately $100 million, this proposed rule is considered a major economic rule, as defined in this section. We note that the approximately $100 million for the projected increase in estimated aggregate proposed LTCH PPS payments from FY 2012 to FY 2013 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also will affect overall payment changes. It also does not include the estimated effect of the proposed 1-year extension of the moratorium on the application of the ''25-percent threshold'' payment adjustment policy on LTCH PPS payments, which is discussed below in section I.J.b.3. of this Appendix.

The projected 1.9 percent increase in estimated proposed payments per discharge from FY 2012 to FY 2013 is attributable to several factors, including the proposed 2.1 percent annual update to the standard Federal rate, the proposed one-time prospective adjustment of −0.98734 (approximately −1.3 percent) to the standard Federal rate, which is not applicable to payments for discharges occurring on or before December 28, 2012, consistent with the statute, and projected increases in estimated HCO and decreases in SSO payments due to a change in the SSO payment methodology effective for discharges occurring on or after December 29, 2012 (as described in section VII.E.3. of the preamble of this proposed rule). As Table IV shows, the change attributable solely to the proposed annual update to the standard Federal rate (2.1 percent), including the proposed one-time prospective adjustment (approximately −1.3 percent) which is not applicable to payments for discharges occurring before December 29, 2012, is projected to result in an increase of 0.9 percent in payments per discharge from FY 2012 to FY 2013, on average, for all LTCHs. This estimated increase of 0.9 percent reflects the proposed 2.1 percent annual update for payments to FY 2013 discharges occurring from October 1, 2012 through December 28, 2012, and the proposed −1.3 percent one-time prospective adjustment factor, which would not apply in determining payments for discharges occurring on or before December 28, 2012, and also includes estimated payments to SSO cases that are paid using special methodologies that are not affected by the annual update to the standard Federal rate. Therefore, the projected increase in payments to the Federal rate is less than the proposed 2.1 percent annual update for FY 2013. Because we are proposing to apply an area wage level budget neutrality factor to the standard Federal rate, the proposed update to the wage data and labor-related share does not impact the proposed increase in payments.

As discussed in section V.B. of the Addendum to this proposed rule, we are proposing to update the wage index values for FY 2013 based on the most recent available data. In addition, we are proposing to decrease the labor-related share from 70.199 percent to 63.217 percent under the LTCH PPS for FY 2013, based on the most recent available data on the relative importance of the proposed labor-related share of operating and capital costs of the proposed FY 2009-based LTCH-specific market basket. We also are proposing an area wage level budget neutrality factor of 0.99903, which reduces the proposed standard Federal rate by approximately 0.1 percent. Therefore, the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments.

We are projecting that LTCHs would experience a decrease in aggregate payments of 0.4 percent in FY 2013 as a result of the expiration of the statutory delay in the application of the very short-stay outlier policy at § 412.529(c)(3), effective for discharges occurring on or after December 29, 2012. Generally, very short-stay outliers are cases that have a length of stay that is less than or equal to one standard deviation from the geometric mean average length of stay of the same DRG under the IPPS. Under the moratorium, very short stay outliers are paid the lowest of: (1) The LTC–DRG payment; (2) 100 percent of cost; (3) 120 percent of the LTCH per diem payment; or (4) a blend of 120 percent of the LTCH per diem amount and the ''IPPS comparable per diem amount'' (the ''blended payment''). With the expiration of the moratorium, in the case of very short-stay outliers, effective for discharges on or after December 29, 2012, the ''blended payment'' will be replaced with only the ''IPPS comparable per diem amount,'' which results in a decrease in payments for these cases.

Table IV below shows the impact of the proposed payment rate and the proposed policy changes on LTCH PPS payments for FY 2013 presented in this proposed rule by comparing estimated FY 2012 payments to estimated FY 2013 payments. The projected increase in payments per discharge from FY 2012 to FY 2013 is 1.9 percent (shown in Column 9). This projected increase in payments is attributable to the impacts of the proposed change to the standard Federal rate (0.9 percent in Column 6), the end of the moratorium on delaying the implementation of the very short-stay outlier policy (−0.4 percent in Column 8), as well as the effect of the estimated increase in proposed payments for HCO cases and SSO cases (1.1 percent, 0.2 percent, respectively). That is, estimated total HCO payments are projected to increase from FY 2012 to FY 2013 in order to ensure that the estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2013. An analysis of the most recent available LTCH PPS claims data (that is, FY 2011 claims data from the December 2011 update of the MedPAR file) indicates that the FY 2012 HCO threshold of $17,931 (as established in the FY 2012 IPPS/LTCH PPS final rule) may-result in HCO payments in FY 2012 that fall below the estimated 8 percent. Specifically, we currently estimate that HCO payments would be approximately 6.9 percent of the estimated total LTCH PPS payments in FY 2012. We estimate that the impact of the increase in HCO payments would result in approximately a 1.1 percent increase in estimated payments from FY 2012 to FY 2013, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2012 to FY 2013 for HCOs, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries. This increase in estimated costs also results in a projected increase in SSO payments of 0.2 percent relative to last year. However, the expiration of the statutory moratorium on the application of the very short-stay outlier policy, effective December 29, 2012, which replaces the ''blended payment'' option with the ''IPPS comparable per diem amount'' option for certain SSO cases (as described in section VII.E.3. of the preamble of this proposed rule) is expected to result in a −0.4 percent change in aggregate payments. The net result of these projected changes in SSO payments in FY 2013 is an estimated change in aggregate payments of −0.2 percent. We note that estimated payments for all SSO cases comprise approximately 13 percent of the estimated total LTCH PPS payments, and estimated payments for HCO cases comprise approximately 8 percent of the estimated total LTCH FY 2013 PPS payments. Payments for HCO cases are based on 80 percent of the estimated cost of the case above the HCO threshold, while the majority of the payments for SSO cases (approximately 59 percent) are based on the estimated cost of the case.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS would result in an increase in estimated aggregate LTCH PPS payments and that the resulting LTCH PPS payment amounts would result in appropriate Medicare payments.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 3.6 percent increase in estimated payments per discharge for FY 2013 as compared to FY 2012 for rural LTCHs that would result from the proposed changes presented in this proposed rule, as well as the effect of estimated changes to HCO and SSO payments. This estimated impact is based on the data for the 27 rural LTCHs in our database (out of 427 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2012 to FY 2013 for rural LTCHs is primarily due to the higher than average impacts from the proposed changes to the area wage level adjustment, specifically, the proposed decrease in the labor-related share from 70.199 to 63.217. Although we are proposing to apply an area wage level budget neutrality factor for proposed changes to the wage indexes and labor-related share to ensure that there is no change in aggregate LTCH PPS payments due to those changes, we estimate rural hospitals would experience a 1.1 percent increase in payments due to the proposed changes to the area wage level adjustment, as shown in Column 7 below. Rural hospitals generally have a wage index of less than 1; therefore, a proposed decrease to the labor-related share results in their proposed wage index reducing a smaller portion of the standard Federal rate, resulting in an estimated increase in payments in FY 2013 as compared to FY 2012.

3. Anticipated Effects of Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

As discussed above in section I.J.1. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2013 relative to FY 2012 of approximately $100 million based on the 427 LTCHs in our database.

b. Expiration of Statutory Delay on Full Implementation of the ''25 Percent Threshold'' Payment Adjustment and Proposed 1-Year Extension

As discussed in section VII.E.2. of the preamble of this proposed rule, the statutory delay in the full application of the ''25 percent threshold'' payment adjustment for LTCHs at § 412.534 and § 412.536 will expire for cost reporting periods beginning on or after July 1, 2012, or October 1, 2012, as applicable. We are proposing a 1-year extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013. We estimate that this proposal will result in a payment impact of approximately $170 million to LTCHs.

c. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS payment is set forth in § 412.515 through § 412.536. In addition to the basic MS–LTC–DRG payment (the standard Federal rate multiplied by the MS–LTC–DRG relative weight), we make adjustments for differences in area wage levels, the COLA for Alaska and Hawaii, and SSOs. Furthermore, LTCHs may also receive HCO payments for those cases that qualify based on the threshold established each year.

To understand the impact of the proposed changes to the LTCH PPS payments presented in this proposed rule on different categories of LTCHs for FY 2013, it is necessary to estimate payments per discharge for FY 2012 using the rates, factors (including the FY 2012 GROUPER (Version 29.0), and relative weights and the policies established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51781 and 51838 through 51844). It is also necessary to estimate the payments per discharge that would be made under the proposed LTCH PPS rates, factors, policies, and GROUPER (proposed Version 30.0) for FY 2013 (as discussed in section VII. of the preamble and section V. of the Addendum to this proposed rule). These estimates of FY 2012 and FY 2013 LTCH PPS payments are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for SSO and HCO cases in each year. We also evaluated the proposed change in estimated FY 2012 payments to estimated FY 2013 payments (on a per discharge basis) for each category of LTCHs. We are proposing a standard Federal rate for FY 2013 of $40,507.48 that includes the proposed 2.1 percent annual update, the proposed area wage budget neutrality factor, and the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately −1.3 percent) that would not apply to payments for discharges occurring on or before December 29, 2012, consistent with statute. Payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed one-time prospective adjustment and instead would be paid based on a standard Federal rate of $41,026.88.

Therefore, we modeled payments so that claims with discharge dates prior to January would be paid on the basis of a rate that does not reflect the proposed one-time prospective adjustment, and claims with discharges in January or after would reflect our proposed standard Federal rate for FY 2013 that reflects the proposed one-time prospective adjustment. Furthermore, because the statutory moratorium on application of the very short-stay outlier policy will expire effective for discharges occurring on or after December 29, 2012, we modeled payments so that claims that would qualify for a payment under the very short-stay outlier policy with discharge dates in October, November, and December are paid based on the ''blended payment'' option, if applicable, and claims that would qualify for a payment under the very short-stay outlier policy with discharges in January through September are paid based on the ''IPPS comparable per diem amount,'' if applicable (as described in section VII.E.3. of the preamble of this proposed rule).

Hospital groups were based on characteristics provided in the OSCAR data, FY 2008 through FY 2009 cost report data in HCRIS, and PSF data. Hospitals with incomplete characteristics were grouped into the ''unknown'' category. Hospital groups included the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

To estimate the impacts of the proposed payment rates and policy changes among the various categories of existing providers, we used LTCH cases from the FY 2011 MedPAR file to estimate payments for FY 2012 and to estimate payments for FY 2013 for 427 LTCHs. We believe that the discharges based on the FY 2011 MedPAR data for the 427 LTCHs in our database, which includes 322 proprietary LTCHs, provide sufficient representation in the MS–LTC–DRGs containing discharges for patients who received LTCH care for the most commonly treated LTCH patients' diagnoses.

d. Calculation of Prospective Payments

For purposes of this impact analysis, to estimate per discharge payments under the LTCH PPS, we simulated payments on a case-by-case basis using LTCH claims from the FY 2011 MedPAR files. For modeling estimated LTCH PPS payments for FY 2012, we used the FY 2012 standard Federal rate (that is, $40,222.05 effective for LTCH discharges occurring on or after October 1, 2011, through September 30, 2012).

For modeling estimated LTCH PPS payments for FY 2013, we used the proposed FY 2013 standard Federal rate of $40,507.48, which includes the proposed one-time prospective adjustment of 0.98734 for payments for discharges occurring on or after December 29, 2012 and through September 30, 2013. As noted above, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately −1.3 percent) would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012 and on or before December 28, 2012 would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88; therefore, for the purpose of payment modeling, claims with discharges occurring October through December were modeled using this proposed payment rate.

The proposed FY 2013 standard Federal rate of $40,507.48 includes the proposed application of an area wage level budget neutrality factor of 0.99903 (as discussed in section V.B.5. of the Addendum to this proposed rule). As noted above, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, this proposed rate would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012 and on or before December 28, 2012 would be paid based on a standard Federal rate of $41,026.88, which also includes the proposed area wage level budget neutrality factor of 0.99903.

Furthermore, in modeling estimated LTCH PPS payments for both FY 2012 and FY 2013 in this impact analysis, we applied the FY 2012 and the proposed FY 2013 adjustments for area wage levels and the proposed COLA for Alaska and Hawaii. Specifically, we adjusted for differences in area wage levels in determining estimated FY 2012 payments using the current LTCH PPS labor-related share of 70.199 percent (76 FR 51766) and the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2012 IPPS/LTCH PPS final rule (and available via the Internet (76 FR 51813)). We also applied the FY 2012 COLA factors shown in the table in section V.C. of the Addendum to that final rule (76 FR 51810) to the FY 2012 nonlabor-related share (29.801 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining the estimated FY 2013 payments using the proposed LTCH PPS FY 2013 labor-related share of 63.217 percent and the proposed FY 2013 wage index values presented in Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (and available via the Internet). We also applied the proposed FY 2013 COLA factors shown in the table in section V.C. of the Addendum of this proposed rule to the proposed FY 2013 nonlabor-related share (36.783 percent) for LTCHs located in Alaska and Hawaii.

As discussed above, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated increase in payments for HCO cases (as described in section V.D. of the Addendum to this proposed rule). In modeling proposed payments for SSO and HCO cases in FY 2013, we applied an inflation factor of 1.055 (determined by OACT) to estimate the costs of each case using the charges reported on the claims in the FY 2011 MedPAR files and the best available CCRs from the December 2011 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2013 in this impact analysis, we used the proposed FY 2013 fixed-loss amount of $15,728 (as discussed in section V.D. of the Addendum to this proposed rule). Finally, in modeling payments for SSO cases, we included the expiration of the statutory moratorium on application of the very short-stay outlier, effective for discharges occurring on or after December 29, 2012, under which the ''blended payment'' option of the SSO payment formula will be replaced with the ''IPPS comparable per diem amount'' for very short-stay outlier cases as discussed in section VII.E.3. of the preamble of this proposed rule.

These impacts reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from the FY 2012 to FY 2013 based on the proposed payment rates and policy changes presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the LTCH PPS among various classifications of LTCHs.

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases.
- The fourth column shows the estimated payment per discharge for FY 2012 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2013 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 due to the proposed update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule) and proposed one-time prospective adjustment (which is not applicable to payments for discharges occurring before December 29, 2012, consistent with the statute).
- The seventh column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and proposed labor-related share), including the proposed application of an area wage level budget neutrality factor (as discussed in section V.B.5. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 due to the expiration of the SSO policy that allowed for qualifying SSO cases to be paid under a blended payment amount based on the LTCH per diem rate and IPPS comparable per diem rate.
- The ninth column shows the percentage change in estimated payments per discharge from FY 2012 (Column 4) to FY 2013 (Column 5) for all proposed changes (and includes the effect of estimated proposed changes to HCO and SSO payments).

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2013

(Estimated FY 2012 payments compared to estimated proposed FY 2013 payments*)

LTCH Classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2012 LTCH PPS payment per case	Average FY 2013 LTCH PPS proposed payment per case [1]	Percent change in estimated payments per discharge from FY 2012 to proposed FY 2013 for the proposed annual update to the federal rate [2]	Percent change in estimated payments per discharge from FY 2012 to FY 2013 for proposed changes to the area wage level adjustment with proposed budget neutrality [3]	Percent change in estimated payments per discharges due to expiration of statutory moratorium on application of the 'very' short-stay SSO payment methodology [4]	Percent change in payments per discharge from FY 2012 to FY 2013 for all proposed changes [5]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
ALL PROVIDERS	427	134,114	38,633	39,381	0.9	0.0	−0.4	1.9
BY LOCATION:								
RURAL	27	6,259	34,325	35,571	1.0	1.1	−0.3	3.6
URBAN	400	127,855	38,844	39,568	0.9	0.0	−0.4	1.9
LARGE	202	73,668	40,827	41,519	0.9	−0.2	−0.4	1.7
OTHER	198	54,187	36,147	36,916	1.0	0.2	−0.5	2.1
BY PARTICIPATION DATE:								
BEFORE OCT. 1983	17	5,848	34,189	35,120	0.9	−0.2	−0.2	2.7
OCT. 1983–SEPT. 1993	44	15,786	41,530	42,286	0.9	−0.1	−0.5	1.8
OCT. 1993–SEPT. 2002	185	62,594	37,886	38,616	1.0	0.0	−0.4	1.9
AFTER OCTOBER 2002	173	48,737	39,142	39,895	1.0	0.0	−0.5	1.9
UNKNOWN PARTICIPATION DATE	8	1,149	40,546	41,096	0.9	−0.3	−0.7	1.4
BY OWNERSHIP TYPE:								
VOLUNTARY	82	19,532	38,899	39,900	0.9	0.2	−0.5	2.6
PROPRIETARY	322	111,475	38,451	39,148	1.0	0.0	−0.4	1.8
GOVERNMENT	14	1,718	44,353	45,172	0.9	−0.4	−0.6	1.8
UNKNOWN OWNERSHIP TYPE	9	1,389	42,411	43,693	0.9	0.9	−0.6	3.0
BY REGION:								
NEW ENGLAND	15	7,333	33,793	34,643	0.9	−0.2	−0.2	2.5
MIDDLE ATLANTIC	31	7,970	41,678	42,233	1.0	−0.1	−0.4	1.3
SOUTH ATLANTIC	60	16,367	41,373	41,951	0.9	−0.1	−0.5	1.4
EAST NORTH CENTRAL	69	20,669	40,014	40,782	1.0	0.2	−0.5	1.9
EAST SOUTH CENTRAL	30	8,411	38,938	39,929	0.9	0.7	−0.4	2.5
WEST NORTH CENTRAL	26	5,374	40,845	41,733	0.9	0.6	−0.5	2.2
WEST SOUTH CENTRAL	139	50,543	34,502	35,415	1.0	0.3	−0.4	2.6
MOUNTAIN	32	5,956	41,996	42,450	0.9	−0.7	−0.4	1.1
PACIFIC	25	11,491	48,388	48,603	0.8	−1.3	−0.4	0.4
BY BED SIZE:								
BEDS: 0–24	31	3,478	34,245	35,055	1.0	0.6	−0.4	2.4
BEDS: 25–49	198	44,578	38,194	38,992	1.0	0.3	−0.5	2.1
BEDS: 50–74	115	36,438	38,667	39,421	1.0	0.0	−0.4	2.0
BEDS: 75–124	46	20,178	41,700	42,290	0.9	−0.3	−0.4	1.4
BEDS: 125–199	23	16,055	37,051	37,804	0.9	−0.1	−0.4	2.0
BEDS: 200+	14	13,387	38,416	39,201	0.9	−0.4	−0.4	2.0

[1] Estimated FY 2013 LTCH PPS payments based on the proposed payment rate and policy changes presented in the preamble and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge from FY 2012 to FY 2013 for the proposed annual update to the standard Federal rate and the proposed one-time prospective adjustment to the standard Federal rate (which would not apply to payments for discharges occurring before December 29, 2012, consistent with the statute), as discussed in section V.A.2. of the Addendum to this proposed rule.

[3] Percent change in estimated payments per discharge from FY 2012 to FY 2013 for proposed changes to the area wage level adjustment at § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharges due to the expiration of the statutory moratorium on application of the very short-stay outlier, effective for discharges occurring on or after December 29, 2012, under which the ''blended payment'' option of the SSO payment formula will be replaced with the ''IPPS comparable per diem amount'' for very short-stay outlier cases as discussed in section VII.E.3. of the preamble of this proposed rule.

[5] Percent change in estimated payments per discharge from FY 2012 LTCH PPS (shown in Column 4) to FY 2013 LTCH PPS (shown in Column 5), including all of the proposed changes presented in the preamble and the Addendum to this proposed rule. Note, this column, which shows the percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge for the proposed annual update to the standard Federal rate (column 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

e. Results

Based on the most recent available data for 427 LTCHs, we have prepared the following summary of the impact (as shown above in Table IV) of the proposed LTCH PPS payment rate and policy changes presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge are expected to increase approximately 1.9 percent, on average, for all LTCHs from FY 2012 to FY 2013 as a result of the proposed payment rate and policy changes presented in this proposed rule, including the expiration of the statutory moratorium on application of the very short-stay outlier policy which utilizes the ''IPPS comparable per diem amount'' payment option, effective for discharges occurring on or after December 29, 2012 (discussed in section VII.E.3. of the preamble of this proposed rule) and an estimated increase in HCO payments. This estimated 1.9 percent increase in LTCH PPS payments per discharge from the FY 2012 to FY 2013 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2013 LTCH PPS payments (using the proposed rate and policies discussed in this proposed rule) to estimated FY 2012 LTCH PPS payments (as described above in section I.J.1. of this Appendix).

We are proposing to establish a standard Federal rate of $40,507.48 for FY 2013. Specifically, we are proposing to update the standard Federal rate for FY 2013 by 2.1 percent, which is based on the latest estimate of the proposed LTCH PPS market basket increase (3.0 percent), the proposed reduction of 0.8 percentage point for the multifactor productivity adjustment, and the 0.1 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. In addition, we are proposing to apply a one-time prospective adjustment of 0.98734 (approximately −1.3 percent) to the standard Federal rate. However, this proposed reduction would not apply to payments for discharges occurring before December 29, 2012, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act. Therefore, payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88. We noted earlier in this section that, for most categories of LTCHs, as shown in Table IV (Column 6), the impact of the increase of 2.1 percent for the proposed annual update to the standard Federal rate and the proposed 0.8 percent update to the standard Federal rate that includes the proposed one-time prospective adjustment of approximately −1.3 percent which would not apply to payments for discharges occurring before December 29, 2012, consistent with the statute, is projected to result in approximately a 0.9 percent increase in estimated payments per discharge for all LTCHs from FY 2012 to FY 2013. That is, for approximately the first 3 months of FY 2013, payments would not reflect the proposed one-time prospective adjustment such that payments would be based on the proposed annual update to the standard Federal rate of 2.1 percent, and for the remaining 9 months of FY 2013, payments would be based on a standard Federal rate that reflects the proposed FY 2013 annual update of 2.1 percent and the proposed one-time prospective adjustment of approximately −1.3 percent. In addition, our estimate of the proposed changes in payments due to the proposed updates to the standard Federal rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the update to the standard Federal rate. For these reasons, we estimate that payments would increase by 0.9 percent due to the proposed update to the Federal rate.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 6 percent of the LTCHs are identified as being located in a rural area, and approximately 5 percent of all LTCH cases are treated in these rural hospitals. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge from FY 2012 to FY 2013 for all hospitals is 1.9 percent for all proposed changes. For rural LTCHs, the percent change for all proposed changes is estimated to be 3.6 percent, while for urban LTCHs, we estimate the increase would be 1.9 percent. Large urban LTCHs are projected to experience an increase of 1.7 percent in estimated payments per discharge from FY 2012 to FY 2013, while other urban LTCHs are projected to experience an increase of 2.1 percent in estimated payments per discharge from FY 2012 to FY 2013, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) after October 2002. Based on the most recent available data, the majority (approximately 47 percent) of the LTCH cases are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and are projected to experience nearly the average increase (1.9 percent) in estimated payments per discharge from FY 2012 to FY 2013, as shown in Table IV.

In the participation category where LTCHs began participating in the Medicare program before October 1983, LTCHs are projected to experience a higher than average percent increase (2.7 percent) in estimated payments per discharge from FY 2012 to FY 2013, as shown in Table IV. Approximately 4 percent of LTCHs began participating in Medicare before October 1983. The LTCHs in this category are projected to experience a lower than average increase in estimated payments because of decreases in payments due to the proposed changes to the area wage adjustment. Approximately 10 percent of LTCHs began participating in Medicare between October 1983 and September 1993. These LTCHs are projected to experience a 1.8 percent increase in estimated payments from FY 2012 to FY 2013. LTCHs that began participating in Medicare after October 2002 currently represent approximately 41 percent of all LTCHs, and are projected to experience an average increase (1.9 percent) in estimated payments from FY 2012 to FY 2013.

(3) Ownership Control

Other than LTCHs whose ownership control type is unknown, LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). We expect that, for these LTCHs in the voluntary category, estimated FY 2013 LTCH payments per discharge would experience a higher than the average increase (2.6 percent) in comparison to estimated payments in FY 2012 primarily because we project the estimated increase in HCO payments to be higher than the average increase for these LTCHs. The majority (75 percent) of LTCHs are identified as proprietary and these LTCHs are projected to experience a nearly average increase (1.8 percent) in estimated payments per discharge from FY 2012 to FY 2013. Finally, government-owned and operated LTCHs are also expected to experience a nearly average increase in payments of 1.8 percent in estimated payments per discharge from FY 2012 to FY 2013.

(4) Census Region

Estimated payments per discharge for FY 2013 are projected to increase for LTCHs located in all regions in comparison to FY 2012. Of the 9 census regions, we project that the increase in estimated payments per discharge would have the largest positive impact on LTCHs in the West South Central, East South Central and New England regions (2.6 percent, 2.5 percent and 2.5 percent respectively as shown in Table IV). The estimated percent increase in payments per discharge from FY 2012 to FY 2013 for those regions is largely attributable to the proposed changes in the area wage level adjustment or proposed updates to the MS–LTC–DRGs classifications and relative weights.

In contrast, LTCHs located in the Pacific region are projected to experience the smallest increase in estimated payments per discharge from FY 2012 to FY 2013. The average estimated increase in payments of 0.4 percent for LTCHs in the Pacific region is primarily due to estimated decreases in payments associated with the proposed changes to the area wage level adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds.

We project that small LTCHs (0–24 beds) would experience a 2.4 percent increase in payments due to increases in the area wage adjustment while large LTCHs (200+ beds) would experience a 2.0 percent increase in payments. LTCHs with between 75 and 124 beds are expected to experience a slightly below average increase in payments per discharge from FY 2012 to FY 2013 (1.4 percent) primarily due to an estimated decreases in their payments from FY 2012 to FY 2013 due to the proposed area wage level adjustment.

4. Effect on the Medicare Program

As noted previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments in FY 2013 relative to FY 2012 of approximately $100 million (or approximately 1.9 percent) for the 427 LTCHs in our database. In addition, the effects of the proposed extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning or after October 1, 2012, and before October 1, 2012, will result in a payment impact of approximately $170 million to LTCHs.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Effects of Proposed Requirements for Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of this proposed rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for FY 2015. We now estimate that approximately 95 hospitals may not receive the full annual percentage increase in any fiscal year. At the time that analysis was prepared, 70 hospitals did not receive the full annual percentage increase in FY 2012.

We are proposing that, for the FY 2015 payment determination, we would remove one chart-abstracted measure and 16 claims-based measures, beginning with January 1, 2012 discharges. We believe that these proposed changes would not have a significant effect on our estimate. We believe that most of these estimated 95 hospitals will be either small rural or small urban hospitals. However, at this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for FY 2015.

In section VIII.A.6. of this preamble, we are proposing, for the FY 2015 payment determination, supplements to the chart validation process for the Hospital IQR Program. As a part of these supplements, we are proposing, for FY 2015 payment determinations and subsequent years, to separate validation for chart-abstracted and HAI measures and to also validate two additional HAI measures, CAUTI and SSI.

Starting with the FY 2015 payment determination, we are proposing a modest increase to the current Hospital IQR Program validation sample of 18 cases per quarter (currently three each for SCIP, AMI, HF, PN, ED/IMM, and candidate CLABSI) to 27 cases per quarter (3 each for SCIP, AMI, HF, PN, ED/IMM, and up to 4 each for CLABSI, CAUTI, and SSI). However, in order not to increase the Hospital IQR validation program's overall burden to hospitals, while expanding some of the requirements, and targeting hospitals with higher levels of concern for data quality, we are proposing to reduce the total sample size of hospitals included in the annual validation random sample from 800 eligible hospitals to 600 eligible hospitals. This includes 400 hospitals in the base sample and up to 200 hospitals in the target sample.

The requirement of an additional 9 charts per hospital submitted for validation, combined with the decreased sample size, will result in approximately 1,800 additional charts per quarter being submitted to CMS by all selected hospitals. We provide payment to hospitals for the cost of sending charts to the CDAC contractor at the rate of 12 cents per page for copying and approximately $4.00 per chart for postage. Our experience shows that the average chart received by the CDAC contractor is approximately 275 pages. Thus, we estimate that we would expend approximately $66,600 per quarter to collect the additional charts we need to validate all measures.

The total requirement of 27 charts per hospital would result in approximately 16,200 charts per quarter being submitted to CMS. Using the assumptions discussed above, for the FY 2015 Hospital IQR Program, we estimate that we would have expenditures of approximately $599,400 per quarter related to the validation requirement. Given that we pay for the data collection effort, we believe that a requirement for 27 charts per hospital per quarter represents a minimal burden to participating hospitals selected for validation.

L. Effects of Proposed PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preamble of this proposed rule, we discuss our proposal to implement the quality data reporting program for PPS-exempt hospitals (PCHs), which we refer to as the PCHQR program, as required under section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act. These quality reporting requirements would affect all PCHs participating in Medicare. PCHs would be required to register with the CDC, the CMS contractor, and QualityNet Web sites and take the proper training in order to be adequately prepared to use the respective systems to submit the data. The anticipated burden to these PCHs consists of the following: (1) The initial registration of the facility with CDC, the CMS contractor, and CMS; (2) training of the appropriate staff members on how to use the CDC agency-based data collection mechanism (CDC/NHSN), the CMS contractor-based collection mechanism for the cancer-specific quality measure data, and CMS (QualityNet) program; (3) the time required for collection and aggregation of data; (4) the time required for entry of the data into the CDC's NHSN data warehouse, CMS contractor's quality measure data warehouse, and QualityNet databases by the PCH's representative.

All PCHs that currently do not already report data to the NHSN would be required to register with the CDC, the CMS contractor, and the CMS/QualityNet and take the proper training in order to be adequately prepared to use the CDC's NHSN data warehouse, the CMS contractor's collection mechanism for data submission, and the CMS QualityNet Web site.

Those PCHs that already report the proposed HAI measures to the NHSN would not be significantly affected because we intend to align our reporting infrastructure with that used by the NHSN. However, for PCHs that do not currently report the two proposed HAI measures to the NHSN, at this time, we have no way to estimate how many PCHs will participate in the PCHQR program. Therefore, we are unable to estimate the burden for these PCHs.

Aside from the statutory requirements, it is important to note that one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to the further the development of health care quality, which, in turn, helps to further our objectives and goals. Health care organizations can use their health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

Even more importantly, we intend to share the information obtained from the PCHQR Program with the public as is required under the statute. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a public user-friendly and relevant format, include, but are not limited to: (1) Keeping the public informed of the quality of care that is being provided in PCHs as a whole; (2) keeping the public informed of the quality of care being provided in specific PCHs; (3) allowing the public to compare and contrast the data about specific PCHs, thus enabling the public to make informed health care decisions regarding PCHs; and (4) providing information about current trends in health care. There are many other public uses for these quality data concerning PCHs. Further, keeping the public informed of quality of care provided in health care has always been of high priority to CMS.

We also seek to align the new PCHQR Program reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

M. Effects of Proposed Hospital Value-Based Purchasing (VBP) Program Requirements

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2013 through a reduction to the FY 2013 base operating MS–DRG payment for each discharge of 1 percent, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5

percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent.

We previously published a detailed analysis of the FY 2013 Hospital VBP Program's impact, based on scoring for two quality domains, in the Hospital Inpatient VBP Program final rule (76 FR 26542 through 26545). Because we are not proposing in this proposed rule to make any changes to the FY 2013 Hospital VBP Program, we do not believe we must provide an additional regulatory impact analysis for the FY 2013 Hospital VBP Program. We are proposing the operational details of the payment adjustment in the preamble of this proposed rule. We believe that these proposals do not have a regulatory impact or financial impact beyond policies already finalized. They are proposals regarding how CMS intends to ensure that the value-based incentive payments made to all hospitals in a fiscal year are equal, in total, to the reduced base operating DRG payment amounts.

In section VIII.C. of the preamble of this proposed rule, we discuss our proposal to add requirements for the Hospital VBP Program. In addition to certain operational and payment details for the FY 2013 Hospital VBP Program, we are making a number of additional proposals related to the FY 2015 and the FY 2016 Hospital VBP Program, including proposed measures, performance periods, performance standards, domain weighting, and other topics.

Specifically, with respect to the FY 2015 Hospital VBP Program, we are proposing to add one additional clinical process of care measure, AMI–10: Statin Prescribed at Discharge, and two additional outcome measures, an AHRQ Patient Safety Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are proposing to add a measure of Medicare Spending per Beneficiary in the Efficiency domain.

With respect to the FY 2016 Hospital VBP Program, we are proposing to adopt four measures: three 30-day mortality measures adopted for FY 2014 and proposed for FY 2015—MORT–30–AMI, MORT–30–HF, and MORT–30–PN—and the AHRQ PSI composite measure. All of these measures are required for the Hospital IQR Program; therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

For future program years, we intend to consider the impacts of Hospital VBP Program policies in the applicable IPPS/LTCH PPS rulemaking vehicle. Because we are not proposing to alter the underlying scoring methodology finalized for the FY 2013 Hospital VBP Program in this proposed rule, we do not believe it appropriate to revise the regulatory impact analysis published in the Hospital Inpatient VBP final rule referenced above. We intend to provide an updated analysis of the Hospital VBP Program's impacts for the FY 2014 program year in the FY 2014 IPPS/LTCH PPS rulemaking.

N. Effects of Proposed New Measures To Be Added to the LTCH Quality Reporting (LTCHQR) Program

In section VIII.D. of the preamble of this proposed rule, we discuss the implementation of section 3004(a) of the Affordable Care Act, which added section 1886(m)(5) to the Act. Section 1886(m)(5) of the Act, further provides that in the case of an LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to the standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by 2 percentage points. The initial requirements for this LTCH Quality Reporting (LTCHQR) Program were finalized in the section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51839 through 51840), we estimated that only a few LTCHs would not receive the full payment update in any fiscal year as a result of not submitting data under the LTCH quality reporting program. At this time, the LTCHQR Program has not been fully implemented, as data collection will not begin until October 1, 2012. However, we believe that statements we made in the FY 2012 IPPS/LTCH PPS final rule regarding the number and types of LTCHs that may not receive the full payment update as a result of failing to submit data to the Secretary under the LTCHQR Program remain valid. We believe that a majority of LTCHs will submit data because they will view the new quality reporting program as an important step in improving the quality of care patients receive in these facilities. We believe that most LTCHs will quickly and easily adapt to this new quality reporting program and find that the benefits of this program outweigh the burdens.

In section VIII.D.3.d. of the preamble of this proposed rule, for FY 2015, we have proposed to retain the three quality measures that were finalized for use in the LTCHQR Program in the FY 2012 IPPS/LTCH PPS final rule. These measures are: (1) Catheter-Associated Urinary Tract Infections (CAUTI); (2) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI); and (3) Pressure Ulcers that are New or Have Worsened. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51780 through 51781), we estimated that the total yearly cost to all LTCH that are paid under the LTCH PPS to report these data (including: NHSN registration and training for the CAUTI and CLABSI quality measures; data submission for all three measures, and monitoring data submission) would be approximately $756,326. In section XI.B.9. of the preamble of this proposed rule, we use this same estimate.

It is important to note that, as part of its endorsement maintenance process under NQF's Patient Safety Measures Project (*http://www.qualityforum.org/projects/patient safety_measures.aspx*), the NQF reviewed the CAUTI and CLABSI measures that we adopted in the FY 2012 IPPS/LTCH final rule. As a result of this review, the NQF expanded the scope of endorsement of these measures to include additional care settings, including LTCHs. We are proposing, in this proposed rule, that the CAUTI and CLABSI measures be adopted in their expanded form for the FY 2014 payment determination. and all subsequent fiscal year payment determinations. We do not anticipate that the expansion of the CAUTI and CLABSI measures will cause any increase in the burden to providers because there will be no change in the way that these data are collected or reported.

In the FY 2012 IPPS/LTCH PPS final rule and in the preamble of this proposed rule, we estimate that the total cost to all LTCHs to report these data, including NHSN registration and training for the CAUTI and CLABSI quality measures; data submission for all three measures, and monitoring data submission would be $756,326. We believe that this remains a valid estimation of the total financial burden that all LTCHs will incur as a result of the LTCHQR Program, even considering that the CAUTI and CLABSI measures were reviewed and expanded by the NQF.

We do not believe that that the burden estimate that we made in the FY 2012 IPPS/LTCH PPS final rule is affected by the expansion of the CAUTI and CLABSI measures because these expanded measures are essentially the same measures that were adopted in the FY 2012 IPPS/LTCH PPS final rule, except that the measure names have been changed and the measures have been expanded so as to be applicable to the LTCH setting. The expanded CAUTI and CLABSI measures make no changes to the way that this data is to be collected and reported by LTCHs. Thus, use of the expanded CAUTI and CLABSI measures will place no additional financial burden on LTCHs. In addition, we believe that this financial burden should remain relatively stable over the first several years of this quality reporting program, subject to normal inflationary increases, such as increased labor wage rates.

In section VIII.D.3.d. of the preamble of this proposed rule, for the FY 2016 LTCHQR Program, we are proposing to add five additional quality measures. These proposed quality measures are: (1) Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); (2) Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682); (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); (4) Ventilator Bundle (NQF #0302); and (5) Restraint Rate per 1,000 Patient Days (not NQF-endorsed).

As we noted previously, the LTCHQR Program has not been fully implemented, as data collection will not begin until October 1, 2012. At this time, we provide estimates of the costs associated with the collection and submission of data in section XI.B.9 of the preamble of this proposed rule.

We invite public comment on the impact that the proposed measures would have on LTCHs.

O. Effects of Proposed Quality Reporting Requirements for Ambulatory Surgical Centers (ASCs)

In section XIV.K. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized quality reporting measures for the CYs 2014, 2015, and 2016 payment determinations under the ASC Quality Reporting Program. In section VIII.E. of the preamble of this proposed rule, we discuss our proposals to adopt requirements for ASCs to report quality data under the ASC Quality Reporting Program in order to be eligible to receive the full ASC annual payment update. We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016 because we do not have data that would allow us to make a reasonable estimate. ASCs have not yet submitted quality data to CMS; therefore, there are no data from previous program operations on which to base an estimate. Further, data from other quality programs would not allow us to make a reasonable estimate. Although we might be able to make a reasonable estimate based on data from other programs with respect to the structural and process of care measures, we are unable to estimate the number of ASCs that would not be eligible to receive the full ASC annual payment update with respect to the submission of QDCs for the claims-based measures. There are two other quality data reporting programs that utilize QDCs reported on claims similar to what we finalized in the ASC Quality Reporting Program: the Physician Quality Reporting System (PQRS) and the E-Prescribing Incentive Program. However, these programs do not have comparable reporting incentives. PQRS currently has no penalty for not meeting reporting requirements, and the E-Prescribing Incentive Program until CY 2012 was solely incentive-based, rather than penalty-based.

P. Effects of Proposed Requirements for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of this proposed rule, we discuss our proposals to implement the IPFQR Program.

1. General Background and Intent for Implementation of the Proposed IPFQR Program

We intend to achieve several goals as we develop and implement the proposed IPFQR Program. One goal of the proposed IPFQR Program is to implement the statutory requirements of section 1886(s)(4) of the Act as added by sections 3401(f)(4) and 10322(a) of the Affordable Care Act. However, in addition, it is important to note that one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to further the development of health care quality, which, in turn, helps to further CMS' objectives and goals. Health care organizations can use such health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

More importantly, as required by the Act, we intend to share the information obtained from the IPFQR Program with the public. These data will be displayed on the CMS Web site. The goals of making these data available to the public in a properly risk-adjusted, public user-friendly and relevant format, include, but are not limited to: (1) Keeping the public informed of the quality of care that is being provided in IPFs as a whole; (2) keeping the public informed of the quality of care being provided in specific IPFs; (3) allowing the public to compare and contrast the data about specific IPFs, thus enabling the public to make informed health care decisions regarding IPFs; and (4) providing information about current trends in health care. There are certainly many other public uses for these quality data concerning IPFs. However, giving the public access to information about the quality of care in specific facilities and keeping the public informed of trends in health care has always been of high priority to CMS.

CMS also seeks to align the new IPFQR Program reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

2. Anticipated Effects

This proposed rule would affect all IPFs participating in Medicare. The facilities will have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the data. The anticipated burden to these providers consists of the following: (1) The initial registration of the facility with QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data into the QualityNet database by the IPF's representative.

We have estimated the burdens associated with IPFs reporting aggregated-level data on QualityNet. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection, submission, and training of personnel for submitting all quality measures is approximately 821 hours in a year for each IPF. Thus, the average hourly burden to each IPF is approximately 68 hours per month. At this time we have no way to estimate how many IPFs will participate in the program. Therefore, we cannot estimate the financial impact.

We are proposing to adopt the quality measures, abstraction methods, population, sampling, and reporting approaches used by TJC. One reason we selected this proposed approach was to minimize the burden on IPFs. There were 1,741 existing IPFs, of which 450 (approximately 26 percent) are currently reporting the proposed measures to TJC. For these IPFs, we estimate that the burden will be minimal.

Q. Effects of Proposed Requirements for Provider and Practitioner Medical Record Deadlines and Claims Denials

In section X. of the preamble of this proposed rule, we discuss changes for practitioners to follow in responding to requests for medical records from Quality Improvement Organizations (QIOs). The proposed changes would require practitioners to adhere to the 21-day and 30-day timeframes in the regulations, which are currently only applicable to providers. In addition, the proposed changes would give QIOs the authority to effectuate claim denials for practitioners who fail to submit the medical records within these timeframes. QIOs have authority to carry out claim denials for providers who fail to submit medical records, but similar provisions do not exist for practitioners. In fact, to this point, the QIOs' only option for practitioners who fail to submit medical records has been to refer the matter to the HHS Inspector General, and it would seem appropriate to identify a step, short of recommending sanctions, for the QIOs to pursue.

On average, QIOs request approximately 2,000 medical records from practitioners each year. In general, requests for medical records from both practitioners and providers are ultimately fulfilled, but the average response time is considerably longer for practitioners than for providers. Because we are working to improve the QIOs' response time in completing various review activities, the proposed application of the timeframes to practitioners is an important step in our efforts. In addition, given that the QIOs have the need for and the statutory authority to request medical records within a reasonable period of time, they have relied on the same 21-day and 30-day timeframes for practitioners. We believe that having the regulatory timeframe and authority to carry out technical denials for providers have generally resulted in providers complying with medical record requests within the required timeframes. In line with this, we believe that having this same regulatory authority for practitioners will result in practitioners complying with medical record requests within their required timeframes, which should, in turn, greatly will reduce the potential for any technical denials. Moreover, because vendors are increasingly being used by providers and practitioners to respond to requests for medical records, the increasing effectiveness of this process could well further diminish any impact of the proposed regulatory changes. While we believe the impact would be insignificant, at this time, we cannot determine the precise number of claim denials that could occur for practitioners as a result of these proposed changes.

R. Alternatives Considered

This proposed rule contains a range of proposed policies. It also provides descriptions of the statutory provisions that are addressed, identifies proposed policies, and presents rationales for our decisions and,

where relevant, alternatives that were considered.

S. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows an overall increase of 0.9 percent in operating payments. We estimate that operating payments would increase by approximately $904 million in FY 2013 relative to FY 2012. In addition, we estimate a savings of $24 million associated with the HACs policies in FY 2013, which is an additional $2 million in savings than in FY 2012. In FY 2012, pursuant to section 1109 of the Affordable Care Act, we distributed an additional $250 million to qualifying hospitals resulting in a decrease of $250 million in payments to hospitals in FY 2013 relative to FY 2012. Furthermore, we estimate that the expiration of the expansion of low-volume payments under sections 3125 and 10314 of the Affordable Care Act in FY 2013 will result in a decrease in payments of $300 million compared to low-volume payments made in FY 2012. Finally, we estimate that our proposal to count labor and delivery bed days in the available bed day count for IME and DSH payments will reduce IME payments by approximately $170 million for FY 2013. These estimates, added to our FY 2013 operating estimate of $904 million, would result in an increase of $182 million for FY 2013. We estimate that capital payments will experience a −0.1 percent decrease in payments per case, as shown in Table III of section I.I. of this Appendix. We project that there would be an $8 million decrease in capital payments in FY 2013 compared to FY 2012. The proposed cumulative operating and capital payments should result in a net increase of $174 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2013. In the impact analysis, we are proposing to use the rates, factors, and policies presented in this proposed rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2013. Accordingly, based on the best available data for the 427 LTCHs in our database, we estimate that FY 2013 LTCH PPS payments would increase approximately $100 million relative to FY 2012. In addition, we estimate that extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, will result in a payment impact of approximately $170 million to LTCHs.

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the proposed change in Medicare payments to providers as a result of the changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2012 TO FY 2013

Category	Transfers
Annualized Monetized Transfers.	$174 million.
From Whom to Whom	Federal Government to IPPS Medicare Providers.
Total	$174 million.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis for the proposed changes under the LTCH PPS for this proposed rule projects an increase in estimated aggregate payments in FY 2013 relative to FY 2012 of approximately $100 million for the 427 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table VI below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to proposed changes to the LTCH PPS. Table VI provides our best estimate of the estimated increase in Medicare payments under the LTCH PPS as a result of the proposed provisions presented in this proposed rule based on the data for the 427 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2012 LTCH PPS TO THE FY 2013 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	Positive transfer—Estimated increase in expenditures: $100 million.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $34.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 33 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/contractingopportunities/sizestandardtopics/tableofsize/index.html*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. Medicare fiscal intermediaries and MACs are not considered to be small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the

Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold level is approximately $136 million. This proposed rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VI. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific rate for SCHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2013, we plan to include the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2013

A. Proposed FY 2013 Inpatient Hospital Update

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2013 as equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas (which is based on IHS Global Insight Inc.'s (IGI's) first quarter 2012 forecast of the FY 2006-based IPPS market basket), subject to a reduction of 2.0 percentage points if the hospital fails to submit quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.1 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Affordable Care Act, as added by section 3401(a) of the Affordable Care Act, state that the application of the multifactor productivity adjustment and the additional FY 2012 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.H.1. of the preamble of this proposed rule, we are proposing a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2012) of 0.8 percent.

Therefore, based on IGI's first quarter 2012 forecast of the FY 2013 market basket increase, we are proposing an applicable percentage increase to the FY 2012 operating standardized amount of 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for economy-wide productivity and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with section 1886(b)(3)(B)(vii) of the Act and our rules. For hospitals that fail to submit quality data, we are proposing an applicable percentage increase to the operating standardized amount of 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of increase of 3.0 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.8 percentage point for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

B. Proposed Update for SCHs for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2013 applicable percentage increase in the hospital-specific rate for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an applicable percentage increase to the hospital-specific rate applicable to SCHs of 2.1 percent for hospitals that submit quality data or 0.1 percent for hospitals that fail to submit quality data.

C. Proposed FY 2013 Puerto Rico Hospital Update

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 2.1 percent.

D. Proposed Update for Hospitals Excluded From the IPPS

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's and cancer hospitals. Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under § 413.40, which also uses section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, cancer hospitals, and RNHCIs are the remaining three types of hospitals still reimbursed under the reasonable cost methodology. We are proposing that the FY 2013 rate-of-increase percentage to be applied to the target amount for children's hospitals, cancer hospitals, and RNHCIs would be the percentage increase in the IPPS operating market basket. For this proposed rule, the current estimate of the FY 2013 IPPS operating market basket percentage increase is 3.0 percent.

E. Proposed Update for LTCHs

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section VII. of the preamble of this proposed rule, we are proposing to establish an update to the LTCH PPS standard Federal rate for FY 2013 based on the full LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 3.0 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.1 percentage point. The productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.8 percent for FY 2013. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2013 be reduced by the ''other adjustment'' at section 1886(m)(4)(C) of the Act, which is 0.1 percentage point. Therefore, based on IGI's

first quarter 2012 forecast of the proposed FY 2013 market basket increase, we are proposing an annual update to the LTCH PPS standard Federal rate of 2.1 percent (that is, the current FY 2013 estimate of the proposed market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for economy-wide productivity and less 0.1 percentage point). Accordingly, we are proposing to apply an update factor of 1.021 in determining the proposed LTCH PPS standard Federal rate for FY 2013. Furthermore, we are proposing to phase in a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) by applying a factor of 0.98734 (or approximately −1.3 percent), which would not be applicable to payments for LTCH PPS discharges occurring on or before December 28, 2012 (consistent with current law).

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY 2013. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, we are recommending an applicable percentage increase to the standardized amount of 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for MFP and less 0.1 percentage point). We are recommending that the same applicable percentage increase apply to SCHs and the Puerto Rico-specific standardized amount.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our proposal for these facilities, we are recommending an update for children's hospitals, cancer hospitals, and RNHCIs of 3.0 percent.

For FY 2013, consistent with policy proposal set forth in section VII. of the preamble of this proposed rule, we are recommending an update of 2.1 percent to the LTCH PPS standard Federal rate.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2012 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates equal to one percent. MedPAC expects Medicare margins to remain low in 2012. At the same time, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care. MedPAC also recommended that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2013 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to one percent, for FY 2013, as discussed above, sections 3401(a) and 10319(a) of the Affordable Care Act amended section 1886(b)(3)(B) of the Act. Section 1886(b)(3)(B) of the Act, as amended by these sections, sets the requirements for the FY 2013 applicable percentage increase. Therefore, we have proposed an applicable percentage increase for FY 2013 of 2.1 percent, provided the hospital submits quality data, consistent with these statutory requirements.

With regard to MedPAC's recommendation that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2013 and MedPAC's recommendation of a 1.0 percent update to gradually recover post overpayments due to documentation and coding changes, we refer readers to section II.D. of the preamble of this proposed rule for a complete discussion of the proposed FY 2013 documentation and coding adjustments. In section II.D. of the preamble of this proposed rule, we are proposing a prospective adjustment of 2.7 percent to the FY 2013 standardized amount to remove the remaining effect of documentation and coding that occurred in FY 2008, FY 2009, and FY 2010. We note that section 7(b)(1)(B) of Pub. L. 110–90 authorized recoupments of overpayments due to documentation and coding improvements for FY 2008 and FY 2009, and under this authority, such recoupments had to be made no later than FY 2012. Accordingly, any recoupments of overpayments due to documentation and coding improvements beyond the authority of section 7(b)(1)(B) of Public Law 110–90 would require changes to current law by Congress.

We also note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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Part III

Office of Personnel Management

5 CFR Parts 213, 302, *315 et al.*
Excepted Service, Career and Career-Conditional Employment; and Pathways Programs; Final Rules

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 213, 302, 315, 330, 334, 362, 531, 536, 537, 550, 575, and 890

RIN 3206–AM34

Excepted Service, Career and Career-Conditional Employment; and Pathways Programs

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing final regulations implementing the Pathways Programs established by E.O. 13562, signed December 27, 2010. As directed by the President, the Pathways Programs provide clear paths to Federal internships and potential careers in Government for students and recent graduates. The Pathways Programs consist of the Internship Program, the Recent Graduates Program and the Presidential Management Fellows Program. Positions in the Pathways Programs are excepted from the competitive service. Participants in these Programs are appointed under the newly created Schedule D of the excepted service.

DATES: This final rule is effective July 10, 2012. Agencies, however, shall have a 6-month transition period following the effective date of the final rule to convert to the Internship Program any students serving under appointments made pursuant to the Student Educational Employment Program and to transition to the new Presidential Management Fellows Program any Fellows currently serving under appointments made pursuant to the existing Presidential Management Fellows Program. In addition, during the transition period, agencies are permitted to make appointments under the Internship and Presidential Management Fellows Programs even if they have not entered into a final Memorandum of Understanding (MOU) with OPM, as required by 5 CFR 362.104. This transition period does not apply to the Recent Graduates Program, and appointments under the Recent Graduate Program may not be made until an MOU is in place.

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SUPPLEMENTARY INFORMATION: In Executive Order 13562, dated December 27, 2010, President Obama established the Pathways Programs, consisting of three streamlined developmental programs: the Internship Program for students; the Recent Graduates Program for people who have completed a qualifying educational program within the preceding 2 years; and the Presidential Management Fellows (PMF) Program for people who obtained a graduate or professional degree within the preceding 2 years. To implement this Executive Order, OPM issued proposed regulations for parts 213, 302, 315, 330, 334, 362, 531, 536, 537, 550, 575, and 890 of title 5, Code of Federal Regulations (5 CFR) on August 5, 2011.

As explained in the proposed regulations, the President is authorized by statute to provide for ''necessary exceptions of positions from the competitive service'' whenever warranted by ''conditions of good administration.'' (5 U.S.C. 3302). In Executive Order 13562, the President found that ''conditions of good administration (specifically, the need to promote employment opportunities for students and recent graduates in the Federal workforce) make necessary an exception to the competitive hiring rules for certain positions in the Federal civil service,'' *i.e.,* those to be filled through the Pathways Programs. (Exec. Order No. 13562, 75 FR 82585 (Dec. 27. 2010)).

OPM's regulations implement the President's order by establishing the framework for each of the three discrete excepted service internship programs for students and recent graduates:

- The Internship Program is for current students. It consolidates two existing internship programs into a single program designed to provide high school, vocational and technical, undergraduate, graduate, and professional students, opportunities to be exposed to the work of Government through Federal internships. It is largely modeled after the existing Student Career Experience Program (SCEP).
- The Recent Graduates Program is a new program that will provide developmental opportunities in Federal jobs for individuals who have recently graduated from qualifying educational institutions or programs.
- The Presidential Management Fellows (PMF) Program has been the Federal Government's premier leadership development program for graduate and professional degree candidates for over three decades. Executive Order 13562 preserves the PMF Program while making it more flexible by, for example, expanding the eligibility window for applicants to include those who have received a qualifying graduate degree within the preceding 2 years.

The appointing authorities for each Pathways Program are contained in Schedule D of the excepted service, a new schedule created by section 7 of Executive Order 13562. The President created this new schedule pursuant to his statutory authority to make necessary exceptions to the competitive hiring rules when warranted by conditions of good administration. His findings to support the exception are set forth in section 1 of the Executive Order. Under the new Schedule D authority, agencies will be able, under OPM's guidance, direction, and oversight, to use excepted service hiring to fill positions from among a particular class of eligible individuals—students and recent graduates. This approach is consistent with long-standing civil service practice under excepted service hiring authorities, including, for example, Schedule A hiring for people with disabilities.

Part 362 of title 5, Code of Federal Regulations (CFR) contains the regulatory requirements for each Pathways Program. Part 362 consists of four subparts. Subpart A contains only those requirements common to all Pathways Programs. Program-specific requirements are set forth in subpart B for the Internship Program, subpart C for the Recent Graduates Program, and subpart D for the PMF Program.

Summary of Comments

OPM received 238 written submissions with comments on the proposed Pathways Programs. A member of Congress, 24 Federal agencies, 8 labor unions representing Federal employees, 74 individual Federal employees, 20 colleges and universities, 11 professional organizations and student unions, 56 current students and recent graduates and 44 other members of the public submitted comments.

OPM did not address comments that are outside the scope of the regulations. One agency wanted to know how current hiring and pay freezes would affect hiring under the Pathways Programs. Some students and recent graduates submitted resumes for employment consideration under the Pathways Programs. Some submissions detailed personal job search experiences. A few were addressed to agency specific programs not related to Pathways. We did not respond to these submissions in this final regulation.

The majority of the comments expressed support for the creation of the Pathways Programs. Multiple commenters emphasized that the Programs are necessary for recruiting and hiring students and recent

graduates and will be beneficial to the Federal Government. Multiple commenters also characterized the Programs as appropriately limited and emphasized the importance of the oversight tools available to OPM under the proposed regulations. Only two of the commenters—both Federal employee unions—questioned the necessity for the Programs, particularly the Recent Graduates Program. A third union also indicated that it had concerns with the Programs. Even these union commenters, however, supported some aspects of the programs.

Several commenters made arguments either for or against the programs in a more general manner, in addition to lodging specific comments on particular regulatory provisions. These are addressed below, at the outset of the discussion. The comments that addressed specific regulatory provisions are addressed in the discussion of the applicable regulatory sections.

As explained in the proposed regulations, each of the Pathways Programs is intended to be limited in scope, transparent, and fair to veterans. They also require an investment from agencies in the training, mentoring, and career development of the individuals who are brought into these Programs. OPM will play a critical oversight role to ensure that agencies comply with the President's direction to use these Programs as a supplement to, rather than a substitute for, the competitive hiring process. It is with these five core principles in mind (limited scope, transparency, fairness to veterans, agency investment, and OPM oversight) that we reviewed the public comments on the proposed regulations.

Responses to Overarching Comments

1. Necessity

Two unions commented that the Pathways Programs are not necessary for the Federal Government to be able to compete with the private sector for high-quality entry-level candidates. Another union called the Pathways regulations a step in the right direction, but raised some concerns about particular provisions.

We disagree with the unions' comments that these programs are unnecessary. In Executive order 13562, the President, exercising his statutory authority, determined that the Pathways Programs are necessary for the Federal government to compete for students and recent graduates. The President summarized his findings of necessity in section 1 of the order:

> The Federal Government benefits from a diverse workforce that includes students and recent graduates, who infuse the workplace with their enthusiasm, talents, and unique perspectives. The existing competitive hiring process for the Federal civil service, however, is structured in a manner that, even at the entry level, favors job applicants who have significant previous work experience. This structure, along with the complexity of the rules governing admission to the career civil service, creates a barrier to recruiting and hiring students and recent graduates. It places the Federal Government at a competitive disadvantage compared to private-sector employers when it comes to hiring qualified applicants for entry-level positions. To compete effectively for students and recent graduates, the Federal Government must improve its recruiting efforts; offer clear paths to Federal internships for students from high school through post-graduate school; offer clear paths to civil service careers for recent graduates; and provide meaningful training, mentoring, and career-development opportunities. Further, exposing students and recent graduates to Federal jobs through internships and similar programs attracts them to careers in the Federal Government and enables agency employers to evaluate them on the job to determine whether they are likely to have successful careers in Government.

In support of its position that the programs are not necessary, one union relies on the current economic environment, specifically the unemployment rate. Essentially, it argues that there is a greater supply of potential workers now than there was in the years when the data was gathered for some of the reports cited by OPM in its notice of proposed rulemaking, when unemployment rates were lower. The union then draws the conclusion that the Federal Government is necessarily more competitive with the private sector now, because there are more qualified applicants who need work.

We disagree. First of all, it is short-sighted to focus on the unemployment rate for any particular time period in determining the necessity for the Programs. These Programs are intended to be enduring and as the economy improves, competition for skilled workers with other sectors will increase.

Further, even in a tight job market, there exists stiff competition among employers for students and recent graduates who display great potential. Citing Bureau of Labor Statistics analysis, one commenter noted that the number of jobs requiring a master's degree will increase by 18 percent from 2008–2018, and the number requiring a doctoral degree will increase by 17 percent during the same period. Three academic commenters and one good government group supported the President's finding that the Pathways Programs are essential to recruiting and hiring students and recent graduates; they warned that the Federal Government would largely miss out on this key segment of the workforce without the Pathways Programs. OPM agrees that the Federal Government must be able to compete for and hire students and recent graduates, who may lack relevant work experience but who possess significant untapped potential. The Pathways Programs are designed to serve this important purpose.

The unions' comments also fail to take into consideration other important and independent justifications for establishing the Pathways Programs. For example, in a report published on February 6, 2012, the Partnership for Public Service, citing data compiled by the National Association of Colleges and Employers, found that only 2.3 percent of some 35,401 students surveyed were interested in a career with the Federal Government. *See http://ourpublicservice.org/OPS/publications/viewcontentdetails.php?id=170.* The Pathways Programs will help promote enthusiasm for a Federal career among this demographic. By providing positive experiences to students and recent graduates, we help debunk negative stereotypes that they and their contemporaries may harbor about working for the Federal Government. We also leave them with a favorable impression of Government work, so that they would be more likely to consider a return to Government service at a later point in their careers. Several academic commenters emphasized the important role played by this aspect of the Programs, citing experience with past internship and fellowship programs to support their conclusions.

One union commented that the fact that a permanent job is not automatically available to all who are appointed to the Recent Graduates Program undermines the Federal Government's ability to attract high-potential candidates through the Program. It contends that an individual with a job offer from the private sector would surely accept that over a Recent Graduate appointment without the promise of conversion. We disagree. High-potential applicants who are interested in a career in public service will be interested in Recent Graduate appointments because the Program will provide a meaningful training and developmental experience, as well as the potential for a permanent job. Based on our experience with the civil service, training and career development are among the attributes most often cited by recent graduates as desirable in employment opportunities.

This commenter also contends that the best indicator of success on the job is experience, and that it would be ''perplexing'' for the Federal Government to ''seek out'' and ''prefer'' inexperienced applicants over those with experience. These Programs are not motivated by any desire to prefer one type of worker over another. As discussed, agencies should use the Pathways Programs as part of an overall workforce planning strategy to ensure that their workforce is diverse and drawn from all segments of society.

Another union suggested that the introduction of ''category rating'' into the competitive service selection process, combined with other improvements to the competitive hiring process, may have eliminated barriers to entry for inexperienced workers. The union contends that this change has not been in place long enough to evaluate its impact on students and recent graduates. The union is correct that category rating allows a hiring official to select from a larger list of best qualified candidates than the so-called ''rule of 3.'' But category rating does not address the advantage held by experienced workers in the competitive examining process. In order to be considered, an individual must make the top quality category that the agency established by performing well in the competitive examining process. Students and recent graduates have not fared well in the examining process because of their lack of work experience. Though we think the move to category rating is a good one for competitive examining overall, we disagree that it addresses the specific needs that the Pathways Programs are narrowly drawn to address.

This union also suggested that a better solution to the problem with recruiting and hiring students and recent graduates is to reform the competitive hiring process itself. This initiative is not inconsistent with improving the competitive hiring process. Rather, it is an efficient, targeted approach to address specific, identified problems with the current approach to entry-level hiring in the Federal Government.

A union commented that any program that focuses on students and recent graduates is demoralizing to temporary employees working at the Forest Service and other land management agencies. The Pathways Programs are not intended to demoralize any other segment of the Federal workforce. Rather, they are intended to provide for a limited exception to the competitive hiring rules to address a specific concern about the Federal Government's ability to interest students and recent graduates in Federal careers and to successfully recruit, hire, and retain them.

2. Schedule D

Multiple comments addressed the new Schedule D, which was created by section 7 of Executive Order 13562 and is the appointing authority for each of the Pathways Programs.

One union criticized the new Schedule D hiring authority as overly broad. The President created Schedule D pursuant to his statutory authority to make necessary exceptions to the regular competitive hiring rules when warranted by conditions of good administration. It is based upon his determination that the need to promote employment opportunities for students and recent graduates in the Federal workforce makes necessary an exception to the competitive rules. OPM's regulations simply implement the President's mandate.

The union also disputes that students and recent graduates constitute a ''class'' or a ''class of persons'' eligible for appointment pursuant to Schedule D. Schedule D was created by the Executive order, which provides that Schedule D shall include ''[p]ositions other than those of a confidential or policy determining character for which the competitive service requirements make impracticable the adequate recruitment of sufficient numbers of students attending qualifying educational institutions or individuals who have recently completed qualifying educational programs.'' Section 2 of the Executive order directs OPM to issue regulations, including ''a description of the positions that executive departments and agencies may fill through the Pathways Programs.'' The regulations provide for agencies to submit to OPM the positions they seek to fill through the Pathways Programs, and OPM can approve or disapprove of the use of the Programs for those positions through the MOU process. Because the President established Schedule D and the class of individuals covered by it through the Executive order, any comments challenging that determination are beyond the scope of these implementing regulations.

One union commented that Pathways Participants may have available to them training and mentoring opportunities that are not available to other agency employees. The union is correct that agencies may implement the Programs in this manner, but it is in keeping with the nature of the Program to provide Pathways Participants with training and mentoring opportunities. These types of programs are designed to leverage the cognitive abilities of students and recent graduates through training, mentorship, and development. The current version of the Presidential Management Fellows Program and the Veterans' Recruitment Appointment authority are examples where program participants receive training and development opportunities that may differ from those offered to individuals hired through the competitive process or through any other hiring authorities.

3. Position Identification

The proposed regulations contain provisions governing how to identify positions that may be filled through the Pathways Programs. One union commented that the regulations improperly delegate to agencies and their components the authority to exempt positions from the competitive service. We disagree. Agencies are required to report to OPM on the types of positions they seek to fill through the Pathways Programs; they are required to have an Memorandum of Understanding (MOU) in place with OPM in order to use the Pathways Programs; and OPM will decide whether or not to approve the types of positions agencies are filling through the Programs through the MOU renewal process.

4. Definitions

The proposed regulations contained a number of definitions. Some commenters requested clarifications to some of the definitions. As discussed below, we have modified some language in the definitions to address these concerns.

Some comments suggested that the definition of ''qualifying educational institution'' should not include a homeschool curriculum. We think it should. States generally recognize homeschooling as an adequate educational alternative, and we believe it is appropriate to defer to the states on this issue. Moreover, the requirements and standards for homeschooling vary widely from state to state or even within a particular state. OPM, therefore, declines to adopt one commenter's suggestion that there should be a specific Government-wide definition of homeschooling for purposes of these regulations. Rather, agencies will be responsible for determining the eligibility of a homeschooled student applicant.

One union commented that, with respect to the Recent Graduates Program, the definition of ''qualifying educational institution'' does not indicate whether high school degrees would qualify an individual for a Recent Graduate appointment. While the proposed regulation did not include

high school in the definition of ''qualifying educational institution,'' they were not specifically excluded, as is our intention. As a result, we have clarified the definition to exclude high school degrees.

An academic commenter raised a different issue with respect to this definition as it pertained to certificate programs. It suggested that the proposed definition is too broad and subject to abuse. We agree. We have adopted the academic commenter's proposed definition, with modification, and defined ''certificate programs'' to mean ''post-secondary education, in a qualifying educational institution, equivalent to at least one academic year of full-time study that is part of an accredited college-level, technical, trade, vocational, or business school curriculum.''

With respect to the PMF Program, a union suggested further clarification of the term ''advanced degree'' to make clear that the Program is open only to those with master's or doctoral degrees or other professional degrees. An academic commenter made the further point that ''advanced degree'' is no longer in use in the educational community. The commenter suggested using the term ''professional or graduate degree'' instead. We agree with both comments. Subpart A now defines ''advanced degree'' as ''a professional or graduate degree.''

5. Memorandum of Understanding (MOU)

The proposed regulations require agencies to execute an MOU (the ''Pathways MOU'') with OPM as a prerequisite to using the Pathways Programs. This requirement generated several comments.

A Senator commented that it is vital that sufficient OPM oversight be built into the regulations to ensure that the new Pathways Programs do not become a substitute for competitive hiring. Union commenters and multiple academic commenters also generally supported rigorous oversight of the Pathways Programs. One academic organization characterized the regulations as creating a ''rigorous and accountable framework.'' One union commended the MOU requirement as a ''positive idea'' that will give OPM ''a foothold on enforcing the Pathways regulations' requirements against employing agencies.''

We agree that rigorous oversight by OPM is important. Such oversight is built into the regulations by a number of requirements, including, for example: (1) The requirement that agencies report to OPM annually on their intended use of the Pathways Programs; (2) the requirement that agencies enter an MOU with OPM in order to use the Pathways Programs; (3) the requirement that agencies assign a Pathways Programs Officer to serve as a point of contact with OPM's Student Programs Office; (4) the requirement that agencies provide OPM with information about opportunities in the Pathways Programs for posting on the Internet; and (5) the authority of the OPM Director to cap the number of conversions to the competitive service from the Programs (which we have modified, as discussed below, to include the power to cap the number of appointments into the Programs, as well).

One union commented that an MOU is not an appropriate vehicle for oversight of agency use of the Pathways Programs. It suggested that the concepts to be addressed in the MOU instead be addressed specifically in the regulations. We disagree. The MOU will be an effective oversight tool and provides a sufficient degree of accountability. We have had success with this type of tool in an analogous context. That is, we routinely execute delegated examining agreements that authorize agencies to perform their own competitive examining and competitive service hiring and have found that to be a useful vehicle for implementation of other recent hiring reform efforts.

The union appears to be specifically concerned that agencies are to include in their MOUs the criteria for conversion. To the extent this comment is suggesting that this criteria should be in the regulations (see comment above), we agree with respect to the minimum requirements and note that they are set forth in the regulations for each Pathways Program—Internship, Recent Graduates, and PMF, respectively. We are also asking agencies to provide information in their MOUs on how they will apply these criteria.

One union commented that the regulations do not provide for any enforcement mechanism to hold an agency accountable for adhering to the terms of its MOU with OPM. It contended that the regulations offer no way for a union or other interested party to complain about an alleged violation of an MOU. We disagree. Any such complaints could be lodged with OPM's Student Programs Office. In addition, we note that complaints can be raised directly with agencies through their Pathways Programs Officer, a position each agency was required to create by Executive Order 13562. Moreover, OPM's office of Merit System Accountability and Compliance (MSAC) will incorporate oversight of the Pathways Programs into its own evaluations of agency human resources programs and also into agency-led evaluations conducted under an agency's human capital accountability system. Also, nothing in the Pathways Programs implementation alters an employee's ability to seek any other relief that would otherwise be available.

Another union commented that the regulations should specify that OPM has the authority to terminate the MOU and rescind an agency's authority to use the Pathways Programs if OPM learns of agency abuse. We agree and that was always our intention. We have modified our regulations to make clear that OPM possess the power to revoke an agency's MOU when OPM finds the agency's practices are inconsistent with the Executive order, regulation, or the MOU.

Multiple agencies also commented on the requirements of the MOU. They posed questions about such matters as: how long they would have to prepare the MOU, whether OPM would provide a template for the MOU, and whether the MOU would apply at the agency level or the component level. One agency thought each Pathways Program should require a separate MOU. Other agency commenters expressed concern regarding the administrative burden of the MOU requirement.

The regulations do not require agencies to establish an MOU within any particular timeframe. During the transition period, agencies are permitted to make appointments under the Internship and Presidential Management Fellows Programs even if they have not entered into a final Memorandum of Understanding (MOU) with OPM, as required. This transition period does not apply to the Recent Graduates Program, and appointments under the Recent Graduate Program may not be made until an MOU is in place.

Several agencies thought the level of detail required in the MOU and the requirement to re-execute the MOU every 2 years were excessive, and they recommended requiring renewal of an MOU only every 5 years. Another agency recommended re-executing the MOU only if the agency decides to make significant changes. We did not adopt the suggestion concerning re-executing the MOU. While we recognize that re-executing the MOU may occasion some administrative burden, that burden is necessary, especially in light of the benefits that having an MOU in place will provide. The MOU will help OPM oversee agencies' use of these Programs, which are to serve as limited exceptions to the regular competitive hiring rules. On the other hand, we understand the

concerns about the level of detail required in the MOU. As a result, we have streamlined the MOU requirements by removing provisions that are not essential to our initial oversight of the Programs. If we find we need additional information concerning an agency's implementation of the Pathways Programs in order to conduct full and complete oversight, we will request the information at that time.

One agency suggested that its policies and procedures may change as the Pathways Programs evolve and become more familiar to agencies. The agency did not think such changes should necessitate updates and re-execution of the MOU. We disagree. If OPM is to conduct rigorous oversight of these Programs, as is our intention, then it is important for regular re-assessment of each agency's use of them. Indeed, the commenter's suggestion that it be permitted to adopt significant changes to agency policies or procedures for a Pathways Program without modifying its MOU is antithetical to this intention. By requiring re-execution of the MOU on a bi-annual basis, we can better assist agencies in complying with the Executive order, these regulations, and the law.

One agency expressed concern that unions will make claims of excessive or inappropriate use under Pathways and wanted to know if OPM had additional recommendations agencies could include in their MOU to help eliminate misconceptions about Pathways. The Programs are designed to be a supplement to the competitive hiring procedures, and not a substitute for them. The Programs are limited in nature and subject to robust OPM oversight. As stated earlier, OPM is working on sample template MOUs, and agencies may work with OPM to include additional items in the MOU that are particular to their circumstances. OPM is also considering additional guidance to agencies to help them use the Programs appropriately, as part of an overall workforce planning strategy.

Another agency expressed concern that the requirement that an MOU be in place before agencies can use the Pathways Programs will impede agencies' abilities to hire students for jobs that will be available soon after the final regulations take effect. This agency requested a transition period that would allow agencies to fill positions under the Pathways Programs during the implementation period needed to complete the MOU. As noted above, we have adopted the agency's suggestion. First, we are going to provide for the final regulations to take effect 60 days after their publication, rather than 30 days. Second, we have created a six-month transition period during which agencies will be able to hire Interns and PMFs even if they have not executed an MOU with OPM. Third, we are working now to have MOU templates in place so that agencies can satisfy the MOU requirement promptly upon the regulations being finalized.

One agency commented that it does not know what the requirement in section 362.104(a)(1)(I)(B) to address in the MOU how it will ''assess candidates'' means, since the regulations require agencies to qualify candidates based on the OPM Qualification Standard. As required by part 302, agency MOUs must identify what process an agency will use to assess candidates for employment in accordance with part 302 under a Pathways Program, *e.g.,* whether applicants will be rated and ranked using a numerical system or whether the agency will use an unranked method using veterans' preference status.

6. Job Announcements

The proposed regulations require agencies to provide information about Pathways Program opportunities to OPM, which will in turn provide such information to the public. One union commented that the regulations should further specify that agencies must post all job announcements for positions in the Pathways Programs on USAJOBS.gov. It contends that this is required by law.

We disagree with the commenter's legal conclusion. As a matter of policy, however, we agree that individuals who are interested in applying for positions in the Pathways Programs should be able to obtain information about the opportunities that are available. This will benefit all members of the public who are interested in and eligible for these Programs, including veterans who may have been out of school for up to 6 years and therefore not have the same access to school career counselors. Thus, we are retaining the provisions in the regulations that require agencies to provide information to OPM about positions, locations, and where to find information to apply for Pathways jobs. OPM will make this information available to the public. Our intention is to do so through USAJOBS.gov, as the commenter suggested.

Some agencies also submitted comments regarding the requirement to provide information about Pathways opportunities to OPM. A few confused the regulatory reporting requirements for accountability and oversight with the requirement to post Pathways opportunities to the public. The reporting requirements, which are found at § 362.109, are separate from the requirement to provide information about Pathways Programs opportunities for OPM to post, found at § 362.105. These separate regulatory requirements serve different purposes. The reporting requirement is intended to encourage agencies to conduct thoughtful workforce planning and to provide OPM with information about the expected use of the Pathways Programs during the forthcoming year—both in particular agencies and across Government—including the specific positions to be filled. The posting requirement is provided to promote transparency and make it easier for students and recent graduates to learn about Pathways Programs opportunities.

Agencies expressed concern that the regulations will prohibit them from engaging in targeted recruitment of students through colleges and universities or specific networks such as NACElink or Experience.com. Similarly, one agency commented that it needed to retain the ability to hire local students and expressed concern over the cost to recruit under the new requirements. The regulations require agencies to provide basic information about Pathways Programs opportunities to OPM, which will then post that information through USAJOBS.gov. However, agencies retain the discretion to determine how they will recruit and accept applications as long as they comply with applicable law and the regulatory procedures of part 302. Nothing in the regulations precludes agencies from undertaking local recruiting efforts or using familiar recruiting networks, so long as they do so in compliance with law. Thus, agencies retain the flexibility to establish guidelines regarding minimum announcement periods, geographic areas of consideration, or additional recruitment sources. However, agencies must follow the appointment procedures in part 302.

An agency expressed concern that the requirement to announce information about Pathways positions would result in an increase in the volume of applicants, which would in turn increase the length of time needed to fill a position and perhaps even make it more difficult to increase diversity in the workforce. In contrast, several comments from schools, unions, and private citizens supported the posting of this information. OPM acknowledges that posting information about Pathways opportunities has the potential to increase the number of applicants and possibly lengthen the amount of time to fill positions under Pathways. Nonetheless, we agree with the

commenters who view the requirement positively and note that Executive Order 13562 requires posting of information about Pathways opportunities. This allows for more transparency in Federal internship programs. Members of the public interested in internship opportunities with the Federal Government—whether they are students, recent graduates, or recently obtained a graduate or professional degree—will now be able to learn about these opportunities through a single portal, USAJOBS.gov. This is the portal to all Federal jobs in the competitive service, so it is a source that job seekers are accustomed to consulting. We also believe that agencies ultimately benefit from having larger numbers of qualified applicants. We disagree that being more transparent about internship opportunities will harm agency diversity efforts. Broader dissemination of Pathways opportunities will facilitate agency efforts to recruit from all segments of society.

7. Caps

The proposed regulations reserve to the Director the authority to set a cap on conversions from the Pathways Programs into the competitive service, as authorized by Executive Order 13562. They do not establish a specific cap. One union suggested that OPM establish a cap from the outset, and that the number of Participants in the Pathways Programs be ''limited to a very small percentage of new hires'' in order for the Federal Government to benefit from the Programs. A second union also urged establishment of an initial cap. Some agencies, on the other hand, suggested there should be no cap. They argued that the size of the Programs should be limited only by Federal agency hiring needs and not be a centrally determined cap. Multiple academic and good government groups also commented that the Programs should not be capped.

The Executive order grants to the OPM Director the discretion to limit the number of Program Participants' Government-wide. It would, of course, be necessary to apply any such limits to individual agencies in order to administer a Government-wide cap. The authority to establish a cap is an important oversight tool, along with the other oversight and accountability components of the Pathways framework.

OPM has decided that it would be premature to impose a cap before we have experience with how agencies use the Programs. OPM expects agencies to use Pathways as a supplemental hiring authority that is part of an overall workforce planning strategy, and not as a substitute for competitive hiring. Indeed, as one commenter noted, the Pathways Programs are inherently limiting—only students and recent graduates are eligible—in ways that previous excepted service programs have not been. OPM reserves the right to implement a cap if we find that the robust oversight mechanisms we have put in place are insufficient. Accordingly, OPM will be monitoring agency use of the Programs through data collection, assess on an annual basis whether to impose any caps, and provide notice of any decision to impose a cap in a manner determined by the Director.

One union commented that if OPM imposes a cap, it should be on the number of individuals hired into the Pathways Programs, as opposed to the number converted to the competitive service. The union is opposed to any cap on the number of Program Participants that are ultimately to be converted to competitive service jobs. The union is concerned that a cap on conversions will result in good employees being let go because of an arbitrary limitation on conversions.

A cap on conversions would naturally limit the number of people hired into the Programs in the first place. It is not in agencies' interests to bring on and develop quality talent, only to let them go after 2 years. We would expect agencies to take into account any caps on conversions when determining how many Pathways Participants to hire in the first place.

Nonetheless, we are mindful of the union's concern that matters outside an agency's control, including, for example, new statutory mandates or restrictions, can upend even the best laid strategic workforce plans. In addition, multiple agencies agreed with the union that any caps imposed on the Program should be placed on Pathways appointments and not conversions. The agencies reasoned that limiting appointments automatically limits conversions. Some agencies also commented that they do not want to train Pathways Participants and then not have the opportunity to convert them due to a Program cap. Accordingly, we are adopting the suggestion offered by the union and agency commenters to allow for a cap on the number of hires into the Pathways Programs. The Director's authority to cap the number of conversions of Pathways Participants and his overall authority to oversee and implement the Programs encompasses the inherent authority to limit the number of individuals hired into the Pathways Programs. Reserving this authority to the Director is in the best interests of administering the Programs. We have modified our regulations accordingly.

A union commented that the regulations give OPM too much discretion in establishing any such caps. The union asked that additional substantive standards be added to the regulations, but did not offer any suggestions on the types of standards to include. Some agencies also questioned what criteria OPM would use in evaluating whether to establish any caps. We agree that it is important to identify the criteria we would consider. That is why section § 362.108 of the regulations contains several substantive standards for the OPM Director to consider in establishing any caps. In response to the comments, we have identified an additional substantive consideration: An agency's use of the Programs to hire a majority of the individuals for any single entry-level position over a period of years would be evidence that the agency is not using the Programs as a supplement to competitive examining. We have modified the regulations to reflect this change.

One agency suggested requiring OPM to assist agencies with the implementation of Pathways by providing training or by assigning OPM personnel as points-of-contact for each agency. The agency also suggested an interagency workgroup to provide agencies the support needed to implement Pathways. OPM recognizes the administrative requirements agencies must follow to implement the Pathways Programs and has been establishing appropriate support mechanisms. Currently each agency is assigned an OPM Human Capital Management Representative who provides agencies with policy assistance. In addition, there are OPM program managers assigned to each Pathways Program who can assist agencies with Pathways implementation. OPM has also established a Pathways Advisory Council consisting of agency representatives to assist OPM in implementation of the Pathways Programs. Such assistance will include providing templates for MOUs and Participant Agreements, and providing information about best practices to agencies.

8. Conversion to the Competitive Service

The proposed regulations set forth the rules governing conversion of successful Pathways Participants to jobs in the competitive service. We received multiple comments regarding the rules on conversion.

Two unions suggested that the opportunity for Interns and Recent Graduates to convert to competitive service positions upon completion of their Programs should be eliminated. The unions contend that Interns and Recent Graduates will obtain enough experience during their Internship and Recent Graduate Programs to be able to compete effectively for positions in the competitive service. The President has already made the determination to allow for conversion, and these regulations simply implement his order. Accordingly, any comments concerning whether to allow for conversion are outside the scope of these regulations.

In any event, OPM believes the opportunity for conversion is essential to the success of these Programs. A major premise of the Pathways Programs is that a good way to evaluate these potential job candidates—*i.e.,* students and recent graduates lacking prior work experience in their field—is through a ''tryout'' in the workplace. That is what the Pathways Programs are intended to provide—a tryout for inexperienced workers who have recently undertaken or completed educational programs. In addition, the Programs encourage agencies to develop their Pathways Participants for careers in Government. We are asking agencies to make an investment in these individuals through mentorship, training, and developmental activities. Agencies should be able to reap the benefits of that investment by retaining those who successfully complete their Programs. This is why we have emphasized that agencies must consider opportunities for conversion when deciding how many people to hire through the Programs; there should be a close correlation.

We also disagree that the work experience obtained through the Internship Program or even through on-the-job experience in the Recent Graduates Program would be sufficient to place those individuals on a level playing field when seeking to obtain a job through the regular competitive hiring process. The research we cited in our notice of proposed rulemaking establishes that the workers with much more experience are being hired to fill entry-level jobs in Government. In any event, as the Executive order established, the Pathways Programs are intended to compete effectively for students and recent graduates and must also offer a clear path to civil service careers. For these reasons, we are not accepting the union's suggestion.

The union also suggested that on-board employees would lose out on career advancement opportunities to Pathways Participants who are ''fast-tracked'' into desirable positions. The union's concern is misplaced. As an initial matter, the Pathways Participants are not being ''fast-tracked'' into any Federal positions. Rather, they are being exposed to the Federal workplace through on-the-job experience that they otherwise would not be able to obtain. Indeed, rather than being ''fast-tracked,'' they are actually being required to complete a developmental program and demonstrate through the course of that Program that they are capable of working in an entry-level Federal job.

In addition, though the Pathways Programs include excepted service appointment authorities, OPM qualification requirements will apply to the Recent Graduates and PMF Programs. For the Internship Program, agencies will have the discretion, as they do under the current student programs, to establish agency-specific qualification requirements or to use OPM qualification requirements. Many agencies use OPM qualification requirements for Interns. In short, either OPM or agency-specific qualifications requirements apply to the Pathways Programs, and an Intern, Recent Graduate, or PMF must meet the applicable qualifications requirements in order to be converted into that job, just as he or she would have to do if seeking the job through the competitive hiring process.

With respect to the Recent Graduates Program, one union objected to the requirement that Recent Graduates complete 2 years of service before gaining eligibility to convert to the competitive service. The union argued that the 2-year period would result in inequitable treatment between people hired through the Recent Graduates Program and those hired through the competitive process into the same job. The difference primarily concerns at what point the individual would be deemed an ''employee'' for purposes of appeal rights under 5 U.S.C. chapter 75. We agree with the union and are modifying our regulations to provide for conversion of Recent Graduates after completion of 1 year in the Program, subject to an exception where there are position-specific training requirements that the individual must complete in order to gain entry into the position or maintain the position.

Because the Executive order provides for conversion to the competitive service, we are not bound by the practice that non-preference eligibles hired into the excepted service only become ''employees'' for chapter 75 purposes after completing 2 years of service. Instead, the Executive order gives OPM the authority to implement the Pathways Programs, including the conversion rule, and we are choosing to provide for conversion after 1 year, at which point the individual would become an ''employee'' for purposes of chapter 75.

We are persuaded that a full 2-year period of evaluation is not necessary. Because the Recent Graduates Program contains training, mentoring, and career development requirements, we would expect and encourage agencies to be closely monitoring Participant performance to ensure the match with the agency is a good one throughout the entire duration of the Program. It is better for all parties involved if the agency makes a conversion decision within the first year. Subject to the exception discussed below, a year is sufficient time for an agency to evaluate a Participant's potential, and the agency should assign work to the Participant within that year that allows him or her to demonstrate the ability to perform the job. By allowing for conversion to occur after 1 year in the Program, we provide for more equal treatment among people hired into the same job, regardless of whether they obtained the job through the Recent Graduates Program or the competitive hiring process.

As mentioned, however, we recognize that agencies may have position-specific training programs that new hires must complete before they can actually begin to perform the duties of the job. In those instances, we would permit agencies to develop a recent graduate program that lasts longer than 1 year, up to a maximum of 2 years. Agencies wishing to use this flexibility must include a provision in their Pathways MOU that describes the training program, including its length. Standard training given to every Federal Government employee, or to every employee of the agency, will not trigger this exception to the 1-year conversion period. Rather, the training must be position-specific and serve as a prerequisite to entry to the job, or continued performance in the job. We think this approach aligns the agency's interest in having a sufficient period of time to evaluate a candidate for conversion with the candidate's interest in obtaining training and career development opportunities.

A union commented that the regulations do not include appropriate standards for assuring that excessive numbers of employees are not hired into the Pathways Programs without being converted to the competitive service at the end of their appointment. It suggested that the regulations should require each agency to identify its plan for converting Pathways Programs

Participants to competitive service positions, and the number of each appointment to be used (term and permanent). We agree with the union's suggestion that agencies should conduct sound workforce planning to maximize the benefit of the Pathways Programs, but we think the specific suggestion offered by the union would be overly prescriptive. Agencies have differing staffing needs and will use the Pathways Programs in different ways. For example, some agencies may have very robust internship programs, where the aim is to provide interns with a good career development opportunity even though opportunities to convert to permanent positions may be limited. The proposed regulations strike an appropriate balance between agency flexibility and the need to provide adequate conversion opportunities for employees.

Another union commented that Program Participants should receive ''due process'' before an agency decision not to convert them based on unsatisfactory performance. The decision to convert or not convert could be based on a host of reasons, including performance, budget, agency priorities, etc. If by due process the union is suggesting that Program Participants receive adverse action rights under chapter 75, the law does not provide for such rights during the initial 2 years of the excepted service appointment (except for preference eligibles who have completed one year of service).

The union also objected to a provision in § 362.106(c), which allows Pathways Participants to convert non-competitively to a position in the competitive service at another agency. The union argues that this provision is inconsistent with the concept of the Pathways MOU because there is no relationship between the receiving agency and OPM or the appointee. This provision was intended to allow for Pathways Participants who successfully complete their Programs, but for whom the employing agency lacks budgetary resources or who is interested in a different career path, to convert to a position at another agency so that the Federal Government continues to benefit from the employing agency's investment in the individual. While we continue to believe that this is a valid policy consideration, the union's comment has led us to re-consider the issue in the context of each specific Program.

With respect to the Internship Program, we are persuaded that the rule that currently applies under SCEP allowing students to convert to positions at other agencies should be retained. Because of uncertainty about the length of time it will take a student to complete his or her degree, certificate, etc., it is more difficult for agencies to conduct workforce planning that accounts for Intern conversion. These individuals are more at risk of losing conversion opportunities due to factors beyond their control, or the control of the agency. Accordingly, we do not think a change in the current rule is justified at this time. We will continue to evaluate this rule, however, and are open to considering changes to it at a later date. In any event, we believe the practice of an Intern working for one agency and then converting to another upon graduation is very rare under the current SCEP.

We have decided, however, to adopt the union's suggestion with respect to the Recent Graduates Program. One of the purposes of the Recent Graduates Program is for the Recent Graduate to have an initial ''try-out'' period with an agency, where he or she can receive on-the-job training, mentoring, and career development and the agency can evaluate the potential of the Recent Grad for a career in Government. We think it best that the Recent Graduate convert to a job at the agency that oversaw this developmental process. It is also noteworthy that the regulations (§ 362.304) allow Recent Graduates to seek a Recent Graduates appointment at another agency during their period of eligibility. This flexibility helps to address our original concern, as Recent Graduates working at agencies with shrinking budgets and personnel could seek an appointment at another agency at which they could complete the Program.

Similarly, the PMF Program currently does not contemplate that a Participant who completes the PMF Program would convert to another agency. Rather, the current regulations require the employing agency to convert the PMF if he or she is certified by the Executive Resources Board (ERB). Though the requirement to convert each PMF has been eliminated in these regulations, the rationale continues to hold. Agencies will be inclined to convert PMFs who are ERB certified because they have invested in their development for 2 years.

9. Waiver

The proposed regulations included a provision granting the OPM Director authority to waive Pathways Program requirements under limited circumstances. A union commented that the waiver is too broad. The union proposes alternative language, namely that waiver should be limited to extraordinary circumstances that would render an agency's compliance with the regulations impracticable or impossible. OPM agrees with the union's position that the waiver provision is too broad. Rather than modify the language, as the union suggested, we have removed the waiver provision entirely from the final regulation. OPM believes elimination of the waiver provision will contribute to better overall Program oversight and administration on the part of participating agencies and that sufficient flexibility is offered by other, narrower already existing waiver authorities available to the OPM Director.

10. Veterans' Preference

OPM regularly consulted with veterans' service organizations during the development of the Pathways Programs, prior to publication of the proposed regulations. The proposed regulations make clear that veterans' preference rules apply to the Pathways Programs.

One union cited favorably the steps OPM has taken to safeguard veterans' preference in the regulations. It nonetheless commented that application of veterans' preference in the excepted service is not transparent and the ability to monitor and enforce application of veterans' preference would be compromised under the new Schedule D. As our regulations make clear, veterans' preference applies to the excepted service, Schedule D is no exception, and ensuring that agencies are properly applying veterans' preference will be a key aspect of our oversight of the Pathways Programs.

A Senator suggested that additional guidance and oversight mechanisms are needed to ensure agency compliance with veterans' preference. The regulations make clear that veterans' preference applies to the Pathways Programs. OPM is also considering further guidance to agencies on how to manage the application and selection process for the Pathways Programs in a manner that is consistent with veterans' preference. As mentioned above, we believe the regulations provide sufficient oversight mechanisms to guard against agency abuse.

A union commented that the Pathways Programs erode veterans' preference by excluding veterans who fail to meet the eligibility criteria for the Programs from applying for positions in the Program. We disagree. The President is authorized by law to make necessary exceptions to the competitive procedures, and he has appropriately done so here. Moreover, OPM has taken appropriate steps to ensure that the

Pathways Programs are fair to veterans. These include requiring that information about Pathways opportunities be posted; specifying that veterans' preference rules apply to the Pathways Programs; and allowing certain veterans up to 6 years from the time of graduation (rather than the standard 2 years) to participate in the Recent Graduates Program. As discussed here, OPM has also included several significant oversight mechanisms in the regulations to ensure that agencies are properly using them as a supplement to competitive hiring, rather than a substitute for it.

One agency commented that it supported veterans' preference but did not believe that application of the preference should disadvantage current students or recent graduates. One agency wanted to know how veterans' preference would apply. Agencies are required to follow part 302 procedures (which includes the application of veterans' preference) when making any Pathways appointment, even if to do so disadvantages current students or recent graduates.

One agency wanted to know how the application of veterans' preference would affect the consideration of priority reemployment candidates under the Pathways Programs. The Pathways Programs do not change the requirements. Agencies must follow the order of consideration in part 302 when filling jobs under the Pathways Programs.

One agency suggested that OPM revisit the application of veterans' preference under the Pathways Programs because the agency believes OPM combined competitive and excepted service procedures for veterans' preference. The same agency also expressed concern that providing veterans' preference under Pathways gives the perception that veterans have an overall advantage and wanted to know how agencies would apply veterans' preference. The Veterans' Preference Act of 1944, as amended, applies to positions in the excepted service. OPM does not have the discretion to except Pathways from this statutory requirement, nor would it agree with an exception as a matter of policy. Further, many veterans may be availing themselves of the GI Bill to complete an education. They deserve to have their preference applied should they seek a Federal job via Pathways. Part 302 contains the regulatory requirements and procedures for the application of veterans' preference in the excepted service.

One agency wanted to eliminate from consideration preference eligibles that do not submit proper documentation. OPM will not adopt this suggestion. Agencies are required to exercise due diligence in affording veterans' preference to eligible applicants and to establish policy and procedures that follow existing regulations. This same agency suggested that OPM add a requirement to the final rule stating agencies are not required to accept late applications from veterans' preference eligibles. We did not adopt this suggestion because it is not necessary. The requirement to accept late applications from 10-point preference eligible veterans as provided in § 332.311 does not apply to filling positions in the excepted service.

11. Age Discrimination

One union questioned whether the Pathways Programs are discriminatory, claiming that the Programs favor younger applicants. The union's concerns are misplaced. First, we emphasize that the intention of these regulations is to provide agencies with options to employ as part of an overall recruiting and hiring strategy that will result in a workforce drawn from all segments of society, including employees of all ages. Second, the Pathways Programs themselves are open to all students and recent graduates, regardless of age. Eligible students and recent graduates will include older individuals who left the workforce and returned to school to prepare themselves for new careers, as well as those who obtained degrees while they took time off from their careers to raise a family. Older veterans who use the new GI Bill to further their education after completing their military service are also eligible to participate in the Pathways Programs.

In short, the Pathways Programs were not intended to discriminate based on age, nor should they have that effect. To the extent that an individual believes that an agency is misusing the Programs in order to discriminate against older applicants, he or she may pursue available legal remedies to address such misuse.

12. Miscellaneous

The provisions for temporary assignment under the Intergovernmental Personnel Act (IPA) in § 332.102 contain a definition of ''employee.'' PMFs, SCEPs, FCIPs and VRAs are included in the definition of employee as examples of excepted service employees eligible under the IPA. OPM removed these excepted service examples contained in 332.102 in the proposed regulations because most of them will become obsolete with the publication of the final Pathways rule. One agency suggested that OPM should replace the examples with the new Pathways Programs rather than deleting the explanatory language altogether. We are not adopting this suggestion because we believe the definition is adequate without examples.

One agency suggested OPM create a special Program identifier code to track Pathways Participants. OPM does not believe such a code is necessary at this time. Each Pathways Program has its own unique appointing authority that can be used to track Participants and Program usage. We will evaluate over time whether this approach is adequate.

One agency asked whether the Pathways Programs will be centrally funded from a source separate from the agency's approved appropriation. The Pathways Programs are not centrally funded. Agencies must fund their own Pathways Programs.

One agency recommended that OPM establish a Pathways alumni group to help with recruitment and mentoring. We will consider this idea. In the meantime, we note that agencies are free to establish these groups themselves.

Several agencies asked OPM to clarify whether the Administrative Careers with America (ACWA) testing is required when filling positions under the Recent Graduates Program and whether OPM will be developing assessment criteria for positions filled through the Recent Graduates Program. ACWA testing is not specifically required. Rather, agencies must use a valid and job-related assessment for all positions (including those formerly covered by ACWA). Agencies can choose to use the OPM assessment or other valid assessments.

Responses to Comments on the Regulations

1. Excepted Service (Part 213)

One agency suggested that OPM amend the final rule by placing the regulatory requirements for the administration of the Pathways Programs in part 213 rather than part 362 because it believes it is confusing to have the requirements for the administration of the Pathways Programs in part 362. We did not adopt this suggestion because we believe it is clearer to maintain the specific Program requirements of the Pathways Programs separate from the broad regulatory requirements for the use of excepted schedules that are contained in part 213. Additionally, the current regulatory requirements for use of the PMF Program are contained in part 362, and we decided that it would be best to have

requirements for each of the three Pathways Programs in the same section of the regulation.

One agency requested clarification regarding an agency's ability to continue to simultaneously fill the same position in both the competitive and excepted service (via Pathways). As discussed above, using Pathways is similar to how agencies currently use the SEEP under Schedule A or the Schedule A for hiring people with disabilities. The Executive order allows the positions to be filled in the excepted service, and then converted to the competitive service at a later date. In general agencies have broad authority to fill a position with any applicable authority, regardless of whether doing so places the position in the excepted service.

One agency suggested we clarify the intent of § 213.102(c)(2) pertaining to targeted recruitment. Section 213.102(c)(2) refers to OPM's authority to remove positions from the competitive service so they can be filled in the excepted service under authorities that target specific groups such as students, recent graduates or people with disabilities. Targeted recruitment can be conducted so long as it is done so consistent with any applicable law and regulations.

Several agencies commented and expressed concern regarding temporary appointments for the Internship Program. One agency noted that ''temporary appointment'' is defined as not-to-exceed 2 years. The same agency asked if temporary appointments would be administered under part 316. Several agencies also expressed concern regarding the impact that provisions regarding service limits and restrictions on refilling positions in § 213.104(b)(1) and (2) would have on their ability to use temporary Interns under Pathways. Temporary appointments in the excepted service, the time limits on them, and exceptions to the time limits remain unchanged. The Pathways Programs are covered by excepted service provisions in both § 213 and § 302, not under § 316. By definition in both the competitive and excepted service, temporary appointments are those initially made not to exceed 1 year. Agencies can extend a temporary appointment up to 1 additional year without OPM approval. Because of the nature of temporary intern appointments and the need to accommodate a student's academic curriculum, they are not subject to the time limitations in § 213.104 as provided in paragraph (b)(3)(ii) of that section. The only change made to § 213.104 is the inclusion of the newly established Schedule D.

2. Employment in the Excepted Service (Part 302)

Our proposed regulations include some changes to part 302, governing employment in the excepted service. Agencies submitted several suggestions on part 302. One agency wanted to know how following part 302 would affect priority reemployment candidates. When filling jobs under the Pathways Programs, agencies must follow the order of consideration in § 302.304, that requires consideration of all qualified candidates on its priority reemployment list before considering other candidates.

One agency suggested OPM amend part 302 to allow, but not require, the use of category rating selection procedures so agencies can consider candidates based on criteria other than veterans' preference or reemployment priority eligibility. OPM is not adopting this suggestion. Under § 302.105, agencies may adopt category rating-like selection procedures, as long as those procedures provide veterans with at least as much preference as they would otherwise receive under the other criteria in part 302. Another agency suggested that OPM modify the final rule to include Schedule D in the list of exemptions from the appointment procedures of part 302 in order to allow agencies to apply veterans' preference as far as administratively feasible. OPM did not adopt this recommendation for several reasons. Excepted service positions are approved for exemption from the appointment procedures of part 302 because the circumstances and conditions required to fill the positions cannot be accommodated under the regulations. Pathways positions do not meet this requirement because agencies are required to provide information on Pathways job opportunities and to identify its excepted service procedures for Pathways Programs applicants in accordance with part 302. A central objective of the Pathways Programs is to establish Federal-wide Programs with consistent policies and procedures. Additionally, the exemption from the appointment procedures of part 302 does not relieve agencies from applying veterans' preference as required by law; rather it allows each agency filling these certain types of positions to determine what procedures it will use to afford eligible veterans their preference in a positive manner. For these reasons, it would not be appropriate to exempt Pathways Programs appointments from the appointment procedures of part 302.

3. Conversion to Career or Career-Conditional Employment (Part 315)

Part 315 of the proposed regulations addresses conversion to the competitive service. Several agencies requested clarification of § 315.713, *Conversions based on service in a Pathways Program,* for Pathways Participants, particularly Interns, converted to the competitive service. We believe the requirements in § 315.713(b), are clear, *i.e.,* people lacking the 3-year service requirement for career tenure will be converted to a career-conditional appointment. However, those requirements must be applied according to the provisions of § 315.201, *Service requirement for career tenure.* Certain types of service are creditable toward career tenure as identified in § 315.201(b), *Creditable service.* Service in any Pathways Program is creditable for career tenure. Because the service requirement for tenure is 3 years, most Pathways Participants will convert to career-conditional unless they have previously attained tenure (completed 3 years of creditable service) in which case those individuals should be converted to a career appointment.

Several agencies requested clarification of § 315.713, *Acquisition of competitive status.* We have clarified the regulation to specify that competitive status is acquired upon completion of the probationary period. Time spent on any Pathways appointment is creditable toward completion of the probationary period requirement for the competitive service. Recent Graduates and PMFs attain competitive status immediately upon conversion, *i.e.,* they have completed their probationary period. Because some Interns can be converted after completing their educational requirements and a minimum of 640 hours of work experience, they will be required to complete the requirements for probationary period after conversion.

One agency commented that some agencies have statutory authority to establish probationary periods of more than a year. They requested a Pathways provision that would allow those agencies to apply the longer probationary periods to Pathways conversions. We did not adopt this suggestion. Agencies with statutory authority to require probationary periods in excess of 1 year generally have an agency-specific appointing authority under the same statute. The Pathways Programs fall under the provisions of title 5. The Pathways Programs authorities cannot be used under other statutory authorities.

Pathways Programs (Part 362)

A. General Provisions (Part 362, Subpart A)

Part 362 of the proposed regulation set forth the requirements for each of the Pathways Programs. The majority of comments we received were generally supportive of the creation of the Pathways Programs and with the overall implementation of the Programs through our regulations. We received many comments, however, about specific regulatory provisions.

Several agencies commented that the structure of the proposed regulations was not consistent in addressing requirements such as trial periods, performance management, and progress evaluation information for each Pathways Program. We agree that some modification for clarity is in order. For example, we placed the performance and progress evaluation requirements in subpart A of the final rule, as they apply to each of the three Programs.

One agency suggested rewording § 362.101(c), which is the requirement that agencies provide for equal employment opportunity in the Pathways Programs, consistent with merit system principles and applicable law. The language we proposed is a more accurate reflection of law regarding equal employment opportunity, and we are retaining the language as it was written.

1. Definitions (§ 362.102)

Several schools suggested we specify schools of public policy and schools of international affairs in the definition of a ''qualifying educational institution'' in § 362.102, *Definitions,* as examples of graduate or professional schools. We did not make this change, because we did not wish to highlight one type of qualifying educational institution to the exclusion of other types.

One agency suggested we redefine ''agency'' to include the Government Printing Office (GPO) in accordance with 5 U.S.C. 2302(a)(2)(C). OPM agrees that the GPO should be included in the definition of ''agency'' and modified the final rule accordingly.

Several agencies suggested OPM provide a definition of ''certificate program'' for the purpose of eligibility under Pathways. We agree and have defined, in § 362.102, ''certificate program'' to mean ''postsecondary education, in a qualifying educational institution, equivalent to at least 1 academic year of full-time study that is part of an accredited college-level, technical, trade, vocational, or business school curriculum.''

One agency asked OPM to modify the final rule by adding apprenticeship programs registered with the Department of Labor to the definition of ''qualifying educational institution.'' OPM is not adopting this suggestion because apprenticeship programs focus on requirements for on-the-job experience rather than education and they are not qualifying educational institutions for the purposes of the Pathways Programs. The Pathways Programs focus on formal education. Nonetheless, the Internship Program is open to students in qualifying technical or trade schools, as is the Recent Graduates Program upon completion of a qualifying technical or trade program.

2. Memorandum of Understanding (§ 362.104)

OPM made edits to this section in consideration of the considerable comments previously discussed. For example, we included new definitions for ''advanced degree'', ''certificate program,'' and ''Participant Agreement'' in § 362.102. We clarified agency requirements in § 362.104 by reordering and renumbering the MOU requirements. Other changes are addressed in the applicable sections of the regulations.

On-Boarding Process (§ 362.104(c)(8))

One agency commented that the on-boarding process should be removed as a MOU requirement because on-boarding processes are different among organizations, processes change from time to time due to requirement changes, etc. The agency recommended that OPM amend the final rule by placing the on-boarding process under agency commitment. We agree with this suggestion and modified the final regulations in § 362.104(c)(8)(iv) to provide an adequate on-boarding process for each Pathways Program.

Pathways Programs Officer (§ 362.104(c)(9))

Several agencies suggested OPM eliminate the grade requirement for the Pathways Programs Officer (PPO) in § 362.104(a)(1)(iv)(A) on the basis that agencies should have the authority to determine the grade level and be held accountable. OPM is not adopting this suggestion. Given the duties and responsibilities of the agency PPO, OPM believes GS–12 is the appropriate minimum grade level.

Participant Agreement (§ 362.106)

We received several agency comments on the Participant Agreement (PA) to be executed with all Pathways Participants.

Several agencies suggested that OPM remove the PA from the MOU and place it in each Pathways Program subpart of the regulations. We agree that it should be removed from the MOU, but disagree that it should be removed from subpart A of the regulations. The PA is a requirement for all Pathways Participants and is appropriately placed in subpart A of the regulations. It is clearer, though, to set it out in a separate section, rather than including it in the MOU section. Accordingly, we have renamed it the Participant Agreement (instead of Pathways Agreement) and placed it in a separate section (§ 362.106, *Participant Agreement*). The remaining subpart A sections were renumbered accordingly.

One agency suggested we require agencies to file the PA in the Participant's Official Personnel File (OPF). OPM is not adopting this suggestion. The PA must be maintained while the Pathways Participant is in the applicable Program. However, once the Participant completes the Program and is separated or converted to a position in the competitive service, the PA is no longer applicable. Therefore, we do not believe it is appropriate to add a requirement that it be filed in the OPF.

The same agency commented that the regulations should provide a similar level of detail as is provided for the Pathways Programs Officer with respect to who could execute and approve the PA, and that the requirements for the PA be stipulated in the MOU. OPM does not believe any changes to the final rule are necessary. Agencies have discretion to determine who signs a PA. Participant Agreement requirements are now contained in § 362.106.

Several agencies suggested more detailed requirements for the PA. For example, one agency suggested adding certain requirements to the Participant Agreement an Intern must meet to continue in the Program, such as Grade Point Average (GPA) or a statement of good academic standing and performance ratings of Fully Successful or above. Some agencies supported removal of the requirement for a 3-way agreement with the Participant, the agency, and the Participant's educational institution, while others do not think the 3-way requirement should be removed. Another stated that it was confusing to have a choice and the requirement should be either kept or removed. Several agencies asked if they would have the flexibility to design Participant Agreements based on agency need and several comments expressed concern over the workload the PA will create.

The Participant Agreement is another administrative requirement that OPM believes is necessary for the successful administration of the Pathways Programs. The regulations provide the minimum requirements of the PA. However, agencies have discretion to tailor PAs for each Pathways Program or even for individual organizations as necessary. An agency may continue to use a 3-way agreement, and it may or may not add GPA requirements for continuation in the Internship Program. We understand the challenges involved with identifying specific agency requirements and creating the necessary Participant Agreements. However, once developed, the PAs provide a powerful communication mechanism that ensures Program Participants understand their appointment provisions, manages expectations of all parties concerned, and identifies expectations for successful completion of a Pathways Program for both the Program Participant and manager.

One agency asked if agencies are obligated to enter into an agreement with the educational institution if the school or college required such an agreement. If an agency wishes to enter into a relationship with an educational institution that requires an agreement, the agency has the discretion to do so.

One agency does not believe the Participant Agreement should be required for Interns hired under the temporary provisions of subpart B. We disagree. Interns hired on a temporary basis should have the same benefit of well-defined expectations as any other Pathways Participant.

Several agencies suggested we provide them with a template Participant Agreement. OPM will provide a PA template for agencies to use at their discretion.

3. Filling Positions (§ 362.105)

Appointments (§ 362.105(c))

One agency suggested including temporary appointments in section § 362.105(c) of the regulations. We did not adopt this suggestion. The use of temporary appointments is applicable to the Internship Program only and is addressed in subpart B. Temporary appointments cannot be made under the Recent Graduates or PMF Programs.

Citizenship (§ 362.105(e))

One agency commented that the citizenship requirements were confusing. This paragraph is to ensure that agencies meet Government-wide requirements for non-citizen hiring and do not inadvertently convert a non-citizen to the competitive service. As with excepted service hiring in general, the law permits agencies to hire non-citizens under the Pathways Programs provided they meet applicable immigration requirements.

Length of Appointments (§ 362.105(g))

Several agency comments requested clarification in this area. One agency asked whether the length of appointment for Recent Graduates and PMFs is to be calculated using consecutive or calendar days. Because calendar days are consecutive, we assume the commenter meant business days or calendar days. Appointments for Recent Graduates and PMFs are calculated by counting consecutive calendar days. Agencies may extend the appointment of a Recent Graduate or PMF for no more than an additional 120 calendar days.

Several agencies asked questions about how the 2-year appointment period would be applied for individuals hired under the Internship Program. The 2-year appointment limit does not apply to individuals hired under the Internship Program. Length of appointments for Interns is addressed in subpart B.

Terminations (§ 362.105(h))

Several agency comments suggested the regulations should state reasons for terminating Pathways Participants, such as not maintaining good standing with their school, or failure to meet the conditions of the Participant Agreement. We are not including these suggestions in the final regulations. This paragraph is simply to inform agencies that Pathways Participants can be terminated in accordance with any applicable laws and regulations pertaining to the excepted service. In response to one agency comment, we added the word ''including'' before ''for misconduct, poor performance, or suitability'' to be clear that we are not attempting to restate the entire universe of reasons that an individual could legitimately be terminated. Agencies are expected to take appropriate personnel actions for any Pathways Participant who is not converted to the competitive service at the end of his or her appointment.

4. Conversion to the Competitive Service (§ 362.107)

One agency suggested we modify § 362.107 specifying that conversions must be made in accordance with the applicable Programs. We have made this modification to the final rule.

Another agency suggested OPM enumerate the exemptions of the Priority Reemployment List in § 362.107. The Priority Reemployment List (PRL) is a mandatory priority placement program for certain current and former excepted service employees to excepted service positions covered in part 302 and is not applicable here. Conversions from a Pathways Program are made to competitive service positions. Because the PRL does not apply to competitive service positions, an exemption is not necessary.

One agency requested that OPM provide the statutory citation that allows a term employee in the competitive service to be noncompetitively converted to a permanent position in the competitive service. The authority to convert from a Pathways Program term to permanent competitive service appointment is provided in Executive Order 13562, section 6, paragraph (c), which was issued under the President's broad statutory authority over the civil service.

5. Program Accountability and Oversight (§ 362.107)

In the proposed regulations, Program accountability and oversight information was contained in a single regulatory section, § 362.107. In response to a number of comments seeking further clarity on these provisions, we have now addressed each topic in its own regulatory section. Section § 362.108 now addresses program oversight and § 362.109 addresses agency reporting requirements.

One agency asked if they should estimate their Pathways hires on a fiscal or calendar year basis. The same agency asked about a process for revising their estimates should it need additional Pathways hires. One agency suggested agencies be allowed to give an approximate number of hires under the Pathways Programs, but not be committed to staying within the initial proposed count.

The reporting requirements for Pathways are two-fold: (1) report an estimated projected use of the Pathways Programs for workforce planning; and (2) report actual Program usage for the previous year. Agencies will be required to report to OPM all positions that they intend to fill through Pathways appointments. The reports serve as an important planning and oversight tool. We anticipate requiring this data on a calendar year basis. We will provide additional guidance on the specific form of the reports we wish to receive. This guidance will allow for agencies to review and revise their projections for a particular year if the need arises.

6. Transition (§ 362.108)

Several agencies suggested OPM provide regulatory guidance on how current student employees and PMFs would transition into Pathways. One agency suggested maintaining the current SCEP conversion authority through April 30, 2013, to allow current SCEPs who graduate before the end of 2012 to complete SCEP work experience and other agency-specific conversion requirements. The agency stated that April 30, 2013, would provide a 120-day conversion period and allow sufficient time to obtain necessary documentation of graduation with the required overall GPA for students graduating in December 2012. The same agency suggested the regulations permit current SCEPs to be converted to the new Internship Program with full credit for their prior SCEP work experience.

OPM appreciates the many questions concerning conversion to the new Programs. We will issue comprehensive guidance for the transition of current STEP, SCEP, and PMF employees to the new Pathways Programs following publication of the final rule. We will consider the agency's comments as we craft that guidance. In addition, as mentioned above, we have provided for a 6-month transition period for the Internship and PMF Program. We cannot, however, adopt the agency's suggestion to retain SCEP through April 2013. By virtue of the executive order, the authority to appoint under SCEP is eliminated on the effective date of these regulations.

B. Internship Program (Part 362, Subpart B)

The rules governing the Internship Program appear in subpart B. A union expressed concern that the Internship Program would undermine the competitive hiring process by enabling an agency to hire an Intern who had completed degree requirements but not yet graduated and then subject the Intern to a lengthy trial period with the potential for termination at the end of the period. The union misreads the scope of the Program. An individual may serve as an Intern only while a student. In order to be eligible for conversion, the individual must accumulate 640 work hours (up to 320 of which may be waived under certain circumstances) while a student. The union's hypothetical could not occur because the Intern would not be able to obtain the requisite number of work hours between completion of degree requirements and graduation.

For these reasons, we decline to adopt the union's additional suggestion that individuals who have less than a half semester of coursework before graduation should be eligible only for the Recent Graduates Program. The individual at that point is still a student; he or she may or may not graduate on schedule, and even if he or she does, the Intern may enroll in another academic program and maintain eligibility for employment as an Intern. It is not uncommon, for example, for students who graduate from college to immediately begin a master's or professional degree program.

The union also argues that internship positions should be limited to entry-level positions up to grade 9 or to grade 11 for science, technology, engineering, or mathematics positions. The union notes that this grade limitation applies in the Recent Graduates Program. Another union also argues for grade limits on Internship Program appointments. Several academic commenters support eliminating the grade limits on Recent Graduates and, presumably, approve of the absence of limits on Interns. Grade limitations on Interns would be a change from the current Student Career Experience Program (SCEP), under which interns are paid according to their qualifications. OPM is not persuaded that it should depart from the existing SCEP rule. Agencies need to be able to compete with the private sector for sought-after students, including those in graduate and professional degree programs.

The union also alleges that a particular agency is currently abusing the SCEP, and that the Internship Program regulations would not prevent the type of abuse being alleged. Without commenting on the particulars of the allegations, we note that each agency would be operating its Internship Program under the oversight of OPM, pursuant to an MOU entered into with OPM, and subject to a cap on their use of the Programs. Any further comment would be outside the scope of the regulation.

Another union commented that the duties of a position to which an Intern is appointed should relate to either the Intern's academic or career goals. We agree with this commenter and have modified the regulation to reflect this requirement. In addition, in response to agency comments, we have modified the regulation to provide agencies the discretion, especially when filling positions that require the completion of specific education, to require degree relatedness.

The union also objected to § 362.204(c) insofar as it allows agencies to waive up to 320 of the 640 work hours requirement for an Intern to convert. The union contends that the criteria for waiver are vague and subject to abuse. A good government group, however, commented in favor of the waiver provision. We agree with the good government commenter. This waiver provision mirrors the existing provision under SCEP, which has not been problematic. Furthermore, we think that the waiver option promotes an incentive for Interns to excel academically and in the workplace, to the benefit of the Government.

The majority of agency comments support the concept that, upon completion of the Internship Program, an Intern should be converted to a position directly related to the Intern's academic training and intern work experience. Two agencies, however, suggested that removal of the requirement was inconsistent with the Program. We disagree with these two commenters. A large majority of General Schedule positions do not have a positive education requirement. Therefore, Interns could qualify for conversion to a position at the appropriate grade level based on their general educational background alone. The agencies will have invested in the development of Interns, and it is in their interests, as well as the taxpayers', to take advantage of that investment by having the Intern continue to work for the agency. Accordingly, though we would encourage agencies to conduct workforce planning and hire interns into a field for which they ultimately have a need to fill permanent positions, it is consistent with the Internship Program to allow agencies lacking a permanent position related to the Intern's field of study and Intern work experience to convert high performing Interns to another career field for which the Intern qualifies. Additionally, time spent on the Internship appointment qualifies as work experience for purposes of evaluating an Intern's qualifications for a particular position.

One agency noted a disparity in having a grade limitation on Recent Graduates (*i.e.,* people with degrees) while no similar limitation exists for Interns (*i.e.,* people working toward a degree). The different rules recognize the different purposes of the Programs. The Internship Program is aimed at recruiting students—including those at the highest levels of study—to work in the Federal Government. In recognition of this purpose, grade levels are not currently limited under SCEP. This allows the Government to compete, for example, for highly educated researchers who are finishing their doctoral programs. The Recent

Graduates Program, on the other hand, is focused on individuals without prior work experience in their chosen field, in recognition of the difficulty they have in securing a Federal job through the competitive hiring process. A grade-level limitation is therefore appropriate for Recent Graduates because the premise is that they lack prior related work experience. Their grade levels are thus tied to the levels for which they could qualify based solely on their education.

One agency suggested OPM add a mentor requirement to the Internship Program rules. OPM is not adopting an across-the-board requirement because some Interns serve for very short periods of time. However, we included a requirement to identify mentorship opportunities in the Participant Agreement with Interns. Moreover, we encourage agencies to provide mentors to the Interns it expects to employ for lengthier periods of time (for example, longer than 12 weeks).

One agency requested that OPM add an authority to allow agencies to convert an Intern serving on a temporary appointment to an Intern appointment. The regulations allow any qualified student to be appointed under the Internship Program on either a temporary (not to exceed 1 year) or time limited (more than 1 year) basis. An agency wishing to change a temporary Intern to an Intern appointment would simply reappoint the individual under § 213.3402(a).

Several agencies and a union suggested OPM define the phrase ''meaningful developmental work.'' OPM is not adopting this suggestion because we do not believe it is appropriate to provide a specific definition in the regulation. The phrase broadly refers to career-related work experience that will enable the individual to successfully work upon conversion to the competitive service. By not adopting a specific definition, we allow agencies and Pathways participants to determine the nature of the developmental work appropriate to the position. In exercising this discretion, agencies should not assign, as an Intern's primary duties, simple administrative or clerical tasks such as scanning a document or filing documents which do not support the Intern's career goals. We would expect agencies and Interns to discuss the nature of their work in connection with executing the Participant Agreement.

Several agencies suggested that Intern appointments be made with a specific not-to-exceed (NTE) date. We are not adopting this suggestion because the appointment authority permits noncompetitive conversion to a permanent job in the competitive service, and some Interns will not be treated as time-limited.

An agency commented that the use of the word ''Intern'' causes confusion since Interns are typically hired to work for no salary or a small stipend to gain work experience. OPM does not agree or share this concern. The Student Employment Educational Program (SEEP) co-existed with part 308, Volunteer Service, for many years and we see no reason why the Internship Program cannot continue to do so. Additionally, volunteer service under part 308 can be considered *creditable service,* under § 362.204, toward an Intern's work requirement for conversion to the competitive service.

Several other agencies expressed concern over losing the ability to use unpaid interns. OPM is not revoking the authority to use student volunteers in part 308.

Several agencies asked whether Interns could be converted to the Recent Graduates Program. The Executive order does not provide authority to convert an Intern to the Recent Graduates Program. Agencies should provide Interns with appropriate, related work experience and training. Upon completion of their education and successful performance of the duties of the Intern position, agencies should convert Interns to competitive service positions. Interns could also apply to the Recent Graduates Program upon completing their educational program requirements.

One agency asked that we clarify the distinction between an Internship for a high school student versus one for a post secondary school student, to address work schedules, appointment limitations and work assignments. There is no difference in the appointment or the Program; however, work schedules, assignments, etc., may vary. The Internship Program is flexible enough to allow agencies to tailor the Program to meet its needs. Agencies may appoint any qualified student to the Internship Program on either a temporary or time limited basis. Appointment limitations, work schedules and work assignments and expectations are required to be addressed in the Participant Agreement.

Several agencies expressed concern that OPM is limiting agencies use of temporary Interns. One agency suggested language to modify the final rule for clarity. OPM has modified the final rule to clarify the appropriate use of temporary Interns. The Supplementary Information accompanying the proposed regulations simply reminded agencies to limit their appointment of temporary Interns because the intent of the Program is for agencies to develop a pipeline of talent for important workforce needs. Agencies may hire temporary Interns as they deem necessary, though, in accordance with agency Pathways hiring procedures, and any limitations that may be established by the Director.

One agency suggested OPM rename the Internship Program the ''Current Student Fellowship Program.'' OPM is not adopting this suggestion because we believe ''Internship Program'' is a better, commonly understood label for the Program.

1. Definitions (§ 362.202)

Several agencies suggested a more specific definition of ''student.'' Some agencies proposed OPM limit the Internship Program only to students attending classes for certain time periods, *e.g.,* those who have completed at least one academic semester. We are not adopting these suggestions. The proposed definition of student is familiar, as it is adapted from the current SEEP, which has served the existing student programs well for many years.

2. Filling Positions (§ 362.203)

One agency suggested OPM modify the regulations to include language, similar to language currently in the SEEP regulations, regarding the use of training funds for Pathways Participants. OPM is not adopting this suggestion. We are not attempting to alter the availability of any of these benefits. We have simply eliminated some provisions currently contained in the SEEP regulations that restate requirements or provisions contained in other CFR parts, such as those pertaining to the use of training funds, tuition assistance, travel and transportation, etc. This avoids lengthy changes to sections of the CFR when a particular regulatory requirement changes.

A school asked whether prior Federal service can be used by agencies to determine qualifications and grade-level limitations for individuals appointed to the Internship Program. Yes. Agencies are required, though, to establish procedures on how they will assess applicants for any Pathways Program.

Eligibility (§ 362.203(b))

An agency suggested OPM add a requirement that a student be in good academic standing to be eligible for an Internship appointment. We have not historically expressly stated a good academic standing requirement and are concerned that by introducing it now,

there will be confusion about what it means. It is our expectation, though, that agencies would only appoint students who are adequately progressing toward completion of their academic program.

Qualifications (§ 362.203(c))

One agency suggested OPM modify the final rule to require students to qualify for the Internship Program based only on education. Though we expect that will be true for the vast majority of Interns, we are preserving the rule under SEEP that a student's prior experience may also be taken into account in determining his or her qualifications in connection with an Intern appointment. That approach has been used successfully for decades. Additionally, the Internship Program will be subject to OPM oversight, including potential caps on the number of Program Participants and OPM's authority to revoke an agency's MOU and thus prohibit it from using the Programs.

Another agency asked OPM to modify the regulations to include a provision allowing agencies to develop their own qualification requirements for the competitive service position to which an Intern converts. We are not adopting this suggestion because the OPM Qualification Standards apply when filling any competitive service position and agencies are responsible for the training and development of Interns. Pathways Participants who meet the OPM Qualification Standard for a particular position are eligible for conversion.

Appointments (§ 362.203(d))

Several agencies submitted comments asking OPM to clarify the appointment time limit for Interns. In addition, several agencies confused appointment time limit with the requirement that the Participant Agreement clearly state an expected NTE date. Interns can be appointed two ways: as a temporary employee (NTE 1 year); or for a period of more than 1 year. Appointments made for more than 1 year do not require a NTE date. However, the Participant Agreement requires an expected end date by which the student will complete all educational requirements of the degree.

Promotion (§ 362.203(e))

Several agencies suggested OPM add instructional language to the regulations stating that the promotion of a temporary Intern is documented as a conversion to a new temporary appointment with a requirement the NTE date remain. OPM is not adopting this suggestion. The service limits and restrictions in § 213.104 on refilling excepted service positions do not apply to the appointment of temporary Interns. Therefore the original NTE date is not applicable.

Classification (§ 362.203(f))

One agency commented that the requirement to classify positions to the 99 series is problematic because there is no distinction between one and two-grade interval positions. We disagree.

Using the -99 series for one and two-grade interval positions affords agencies the greatest amount of flexibility when hiring individuals into developmental type programs. Because these individuals are ''trainees'' they are not restricted to the types of work that is normally associated with a specific series. In addition, an entire job family (*e.g.,* 300) of positions will be available at the time of conversion based on the individual's qualifications and the agency's needs. Agencies can differentiate between one grade and two-grade interval positions based on the education level of the employee (*e.g.,* below Baccalaureate level, one grade interval), based on the journeymen level of the target position (*e.g.,* GS 12 full performance level, two grade interval), documented advancement opportunities (career ladders) in the participant's agreement.

Another agency suggested we add the requirement to classify wage grade intern positions to the 01 series. We are adopting this suggestion and have modified the regulations. We did not intend to limit Internship appointments to General Schedule positions; therefore we are clarifying that agencies can make Internship appointments to either General Schedule or Wage Grade positions.

Schedules (§ 362.203(g))

Two agencies commented on work schedules. One suggested OPM amend the final rule by specifying the number of hours a student may work. We did not amend the final rule because the regulations specify an Intern may work a full or part-time schedule. Interns agreeing to work a full-time schedule must work 40 hours per week. Part-time schedules are generally considered to fall between 16 and 32 hours per week. Interns are covered by the same rules for hours of duty contained in part 610 of the CFR.

Another agency suggested we modify the final rule to include an intermittent work schedule. We did not modify the final rule because we do not believe an intermittent work schedule is appropriate for an Intern. Employees on an intermittent work schedule do not have a regularly-scheduled tour of duty; they have no set hours of duty or days of work every week. This is not conducive for students with a set academic schedule or for Intern appointments intended to train an employee for permanent employment.

Breaks in Program (§ 362.203(h))

Most commenting agencies felt the rule about breaks in program, under the SEEP, should be maintained. One agency asked OPM to modify the final rule to allow only one break in Program per appointment. Rules about breaks in Program are solely at an agency's discretion. Therefore, OPM will maintain the current SEEP provisions regarding breaks in program.

3. Conversion to the Competitive Service (§ 362.204)

One school suggested OPM remove the 120-day requirement for conversion so Interns working during summer months would be eligible for conversion upon completion of his or her academic requirements. OPM is not adopting this suggestion, as it appears to be based on a misunderstanding of how the 120-day period works. The 120-day administrative period begins when the Intern completes his or her academic course of study. In other words, the agency has 120 days after the Intern completes all academic requirements of his or her course of study to convert the Intern to the competitive service.

Several agency commenters asked whether the requirement to complete an academic course of study could include a variety of certificate programs, *e.g.,* several 2-week programs completed over a period of 2 years. Short-term training programs that award certificates for completion are not considered an academic course of study. Because of the many comments received regarding certificate programs, OPM modified the regulations to include a definition of ''certificate program'' in subpart A.

One agency asked whether third-party interns (*i.e.,* non-Federal interns) can convert directly into the competitive service. The Pathways Programs do not allow a non-Federal intern to be directly appointed to the competitive service. Up to 320 hours of service as a third-party intern, however, counts toward conversion, if the student subsequently is appointed to the Internship Program.

Several agencies asked OPM to clarify the Internship rules regarding creditable work experience and waiver of work experience for conversion. We agree with the agencies that further clarification of the requirements in the proposed rule is in order. Therefore, we

modified the final rule by restructuring this section as follows: (a) Contains the conversion authority; (b) lists the conversion requirements an Intern must meet for eligibility, such as 640 hours of work experience; and (c) addresses creditable work experience. Paragraph (d) contains the waiver provision. Agencies may waive up to one-half, which is 320 hours, of the work experience requirement for outstanding performers who also have a 3.5 or better grade point average. Paragraph (e) makes it clear that agencies may not credit or waive, or any combination thereof, more than 320 hours of the 640-hour work experience requirement.

Another agency suggested that agencies should be required to document the credit of work experience or waivers. We are not adopting this suggestion because agencies have the flexibility to establish such a requirement should they choose to do so. Additionally, the Internship Program mirrors the existing SEEP, which does not have such a requirement.

Another agency suggested that any experience creditable toward the 640-hour work experience should be directly related to an Intern's career path and academic study. We agree in part. We modified the final rule to require that creditable work experience must be comparable to the work experience of the Internship appointment. For consistency, we did not adopt the suggestion to require the creditable service to directly relate to an Intern's academic study because it is not a requirement of the Internship Program itself.

Several agencies asked OPM to modify the final rule to require that Interns be rated Fully Successful or above to be eligible for conversion. We have not historically expressly stated a minimum rating for student conversion and are concerned that by introducing it now, there will be confusion about what it means. It is our expectation, though, that agencies would only convert students who are performing acceptably, as reflected in any formal ratings of record they may have achieved.

One agency suggested OPM lower the Grade Point Average (GPA) requirement under the waiver provision for Interns, stating a 3.5 GPA requirement to be very restrictive. The agency also suggested that many schools no longer use a ranking system. OPM did not adopt this suggestion because we believe there must be sufficient support to waive one-half of the work requirement. The waiver provision allows agencies to waive up to 320 hours of the 640-hour work requirement based exclusively on a high potential that must be supported by exceptional academic and job performance. Also, this standard mirrors the current SCEP standard.

Another agency asked OPM to change the waiver requirement for exceptional job performance by modifying the final rule to state that exceptional job performance can be demonstrated by a performance rating of Fully Successful or higher. OPM is not accepting this suggestion because we do not believe a Fully Successful rating demonstrates exceptional job performance. The waiver provision allows agencies to waive up to 320 hours of the 640-hour work requirement based exclusively on a high potential that must be supported by exceptional academic and job performance.

OPM received several comments simply supporting or opposing the credit or waiver of 320 hours of work experience. These comments offered nothing further than the simple statement of support or opposition, and no response is necessary.

One agency asked if performance plans are required for Interns. Yes, Pathways Participants are Federal employees subject to performance management provisions as specified in part 430. OPM modified the final rule in § 362.105(h) for clarity.

4. Reduction in Force and Terminations (§ 362.205)

One agency commented that tenure group 0 does not appear in § 351.502. The agency suggested OPM revise the regulatory text in either this section or § 351.502. We are not adopting this suggestion. Tenure group 0 is not included in § 351.502 because it is not covered by RIF regulations; thus, employees who have a tenure group status of 0 have no RIF rights.

Several agencies asked OPM to clarify tenure codes for Interns. We agree with this suggestion and modified the final rule to clearly state that Interns hired for more than 1 year are placed in tenure group II; temporary Interns (hired not to exceed 1 year) are placed in tenure group 0; temporary Interns extended for an additional year are placed in tenure group III.

Several agencies asked OPM to modify the final rule to clarify appeal rights for Interns. We did not adopt this suggestion because Pathways Interns are Federal employees subject to the same appeal rights under chapter 75 of title 5, United States Code as any other employee. Since the provisions for appeal rights are covered under another rule, we will not restate them under this part.

One agency suggested that OPM clarify information pertaining to termination based on conduct and performance. We are not making this change because Pathways Participants are Federal employees and are subject to regulations on terminations for conduct and performance in parts 432 and 752.

C. Recent Graduates Program (Part 362, Subpart C)

The rules governing the Recent Graduates Program are in subpart C.

A union commented that agencies should be required to create training solely for Recent Graduates Program Participants that is different from the standard training offered to all employees at the agency. We agree, as this is the intent of the regulation. Section 362.301 of the proposed regulation addresses this issue.

The union also commented that the Recent Graduates Program should not permit an agency to hire whole groups of entry-level employees and then convert them to term appointments. It would be highly unusual for agencies to take the course of action described by the union. The intent behind allowing agencies to convert Pathways Participants to term appointments is to cover those instances where budgets and other workforce requirements preclude an agency from converting an individual to a permanent position. Because a term appointment can be made for up to 4 years, the agency may be able to recover and subsequently offer that term employee a permanent position. Again, agency practices in implementing the Pathways Programs will have to comply with the MOU and will be subject to OPM oversight, and we will address any concerns along the lines of what the union posits in its comment through the MOU process.

Another union commented that eligibility for the Recent Graduates Program should be limited to those completing the requirements for their degree or certificate within 1 year, rather than 2. The union contends that the narrower window keeps the Program's focus on those who have graduated most recently. Another commenter specifically applauded the 2-year window. The 2-year eligibility window is required by the Executive order, and we have no discretion to adopt the commenter's suggestion. Moreover, we disagree with the union commenter's premise that those having completed their degree or certificate requirements within the preceding 2 years are not recent graduates. It takes time for many graduates to obtain their first job following graduation (months and even years in some cases), so many will not have an opportunity to gain much experience during their first year

that would allow them to compete in the normal competitive process in year two.

One agency requested that any individual who graduated between the date the Federal Career Intern Program was abolished (February 28, 2011) and the date these regulations take effect should have an extended window of eligibility. We reject this suggestion because the Recent Graduates Program was developed independent of the FCIP based on OPM's analysis of the Federal Government's ability to recruit, hire, and retain students and recent graduates. It would therefore not be appropriate to tie eligibility for the Recent Graduates Program in any way to the FCIP.

We are, however, sympathetic to those who graduated during the period starting when President Obama issued Executive Order 13562 (December 27, 2010) through the date these regulations take effect. The Executive order directed that this Program be created, and these graduates should not be disadvantaged as a result of the length of time it takes to issue implementing regulations. Accordingly, we think it is fair and equitable to allow anyone who would have become eligible for the Recent Graduates Program after the date Executive Order 13562 was issued and before the final regulations take effect to have 2 full years of eligibility from the date the final regulations take effect. We expect this change will have the largest impact on the May 2011 graduates, who otherwise would have only had 1 year of eligibility under the Program. OPM will provide additional instructions in the transition guidance.

One union also emphasized its view that it is important that Recent Graduate opportunities apply only to entry-level positions. We agree with the commenter and have amended § 362.301 to specifically reference entry-level positions.

1. Program Administration (§ 362.301)

Mentor (§ 362.301(a))

One agency asked OPM to define what we meant by the requirement to assign a mentor from an ''appropriate level'' outside the Recent Graduate's chain of command. We have reconsidered this issue and now conclude that the level of the mentor assigned should be left solely to the agency's discretion. We intend to allow agencies the discretion to determine mentor grade levels, as agency decisions can be made based on any one of a number of factors such as, on a case-by-case basis, according to job series, or according to the grade level of the Recent Graduate.

Training (§ 362.301(c))

One agency asked OPM to explain the meaning of ''formal'' training in § 362.301(c). For the purposes of the Recent Graduates Program, ''formal'' training is any structured, career-related training.

2. Eligibility (§ 362.302)

Several agencies requested that OPM clarify the eligibility requirements for participation in the Recent Graduates Program. Recent Graduates have 2 years from the date they complete their educational requirements to apply to the Recent Graduates Program. Applicants who apply to Recent Graduates job announcements within the 2-year time limit may be considered and appointed even if the appointment occurs after the 2-year time limit. As mentioned, we are providing 2 full years from the final date of these regulations for anyone graduating since the Executive order was issued on December 27, 2010, who otherwise meets all of the eligibility requirements of the Recent Graduates Program.

Several agencies asked OPM to provide situational examples on the extension of eligibility for veterans in § 362.302(b)(2). OPM will issue transition guidance that will contain situational examples to clarify how to extend the 2-year eligibility period for veterans precluded from applying to the Recent Graduates Program due to military service.

One agency suggested OPM modify the final rule to include Peace Corps and VISTA volunteers in the extension of eligibility because of a military service obligation provided in § 362.302(b)(2). The extension of eligibility was narrowly tailored to address the unique circumstances of service members. We are not persuaded that the exception should be extended beyond that population, nor is there authority to do so under the Executive order.

One commenter suggested OPM modify the military extension criteria to provide a 2-year eligibility period for any veteran completing degree requirements while on active duty. We are not adopting this suggestion because the requirements of the Executive order are to provide an eligibility extension to individuals who enter active military duty after completion of their educational requirements.

One agency asked OPM to allow agencies to extend the eligibility period for veterans beyond 6 years. The 6-year window was established in the Executive order, and we are without authority to extend it further.

One agency suggested OPM change the eligibility criterion in § 362.302 from ''completion of all requirements of an academic course of study'' to ''must have obtained a qualifying degree.'' The agency believes that, as written, the requirements will be administratively burdensome to agencies, applicants and educational institutions. It also states that the requirement will result in improper appointments or inadequate consideration of candidates. Additionally, it states that the suggested change aligns more closely with the requirements of the Executive order. OPM is not adopting this suggestion because the requirement to ''complete all requirements of an academic course of study'' has been effective under the current SEEP. Additionally, requiring the graduate to be in receipt of the diploma or certificate can, in many cases, disadvantage the recent graduate. We understand it is not uncommon for individuals to complete their academic course of study and then not receive their certificate or degree for months, depending on the procedures of the particular school.

One agency suggested that OPM modify the final rule in § 362.302 to be consistent with language used in other sections of the proposed rule regarding the completion of educational requirements. We agree that eligibility criteria should be consistently stated. We have modified the final rule in § 362.302 to state the eligibility as ''2 years from the date all requirements of an academic course of study leading to a qualifying associate's, bachelor's, master's, professional, doctorate, vocational or technical degree or certificate from a qualifying educational institution are met.'' This generally means the individual is considered a Recent Graduate upon completion of all required coursework and final exams, not the date the graduate receives the degree or certificate.

3. Filling Positions (§ 362.303)

Announcements (§ 362.303(a))

One agency suggested that OPM modify the final rule to require agencies to fill Recent Graduate positions within a certain time period of the announcement, for example 90 or 120 days. We are not adopting the agency's suggestion because we do not believe it is appropriate to impose a hard deadline on agency hiring actions. For example, we would not want to prevent agencies from participating in on campus fall recruiting events for positions to be

filled the following spring, after the candidates graduate.

Appointments (§ 362.303(b))

One agency asked OPM to define ''initial appointment'' as referenced in § 362.303(b). For the purposes of Pathways, ''initial appointment'' means an individual's first Pathways appointment in any particular agency.

The same agency asked if Recent Graduates appointments can be made at the full performance-level of a position. Appointments under the Recent Graduates Program may not be made to a full-performance level position. Recent Graduate appointments must have career advancement opportunities, *i.e.* they must be career ladder positions.

Section 362.303(b)(3)(i) through (iv) allows Recent Graduates filling certain science, technology, engineering, and mathematics (STEM) positions to be appointed up to the GS–11 grade level. An agency asked OPM to clarify whether additional occupations, other than STEM, would be included to allow initial appointment above the GS–9 grade level. They would not.

The same agency asked OPM to include a list of science, technology, engineering, or mathematics (STEM) occupations, as referenced in § 362.303(b)(3)(ii), in the final rule. OPM refers the agency to the listing of STEM occupational families appearing in the Handbook of Occupational Groups and Families, available on the OPM Web site.

Several schools suggested OPM remove the grade-level limitations of the Recent Graduates Program to allow work-related experience and additional skills to be used to qualify for appointment up to a GS–12. OPM is not adopting this suggestion because the point of this Program is to allow individuals to qualify for jobs based solely on their education.

Extensions (§ 362.303(c))

Several agencies suggested OPM include a provision in the final rules allowing OPM to approve appointment extensions, not to exceed 1 year, for Recent Graduate appointments. OPM is not adopting this suggestion because the Executive order does not provide OPM the authority to do so. Recent Graduate appointments may only be extended up to a period of 120 days under the employing agencies' procedures. Agencies may, of course, continue to provide training, mentoring, and career development opportunities at their discretion.

Qualifications (§ 362.303(d))

Section 362.303(d) requires agencies to fill Recent Graduates positions using the OPM Qualification Standard for the position being filled. Several agencies asked OPM to modify the final rule to allow the use of agency-developed qualification standards. We are not adopting this suggestion because we do not have the authority to do so under the Executive order, which requires use of OPM Qualification Standards.

Promotions (§ 362.303(e))

One agency suggested OPM add a provision to allow agencies to make accelerated promotions for Recent Graduates. We are not adopting this suggestion. The purpose of the Program is to provide a developmental experience designed to lead to a Federal career. Accelerated promotions are not consistent with the purpose of the Recent Graduates Program.

Trial Period (§ 362.303(f))

One agency asked OPM to clarify trial period for Recent Graduates. Specifically, the agency requested clarification of the reference to § 315.802 which applies to probationary periods in the competitive service. Because recent graduates must work for at least one year prior to conversion, they will have completed their probationary period upon conversion. No further trial period following conversion is available.

4. Movement Between Agencies (§ 362.304)

Several agencies asked OPM to clarify the provisions in § 362.304. Specifically, they asked if the new agency can require the Recent Graduates to begin a new employment period for conversion eligibility. An agency that hires a current Recent Graduate into its Program cannot require the Recent Graduate to start a new Recent Graduate appointment. The agency must convert the Recent Graduate without a break in service, and the employee will be eligible for conversion upon completion of the gaining agency's Program plus any agency-approved extension not to exceed 120 days. This applies regardless of the position series the Recent Graduate is appointed to in either agency.

5. Reduction in Force and Terminations (§ 362.305)

One agency suggested OPM clarify information pertaining to termination of employment based on conduct and performance. Another suggested we add language pertaining to appeal rights for Recent Graduates. OPM is not adopting these suggestions because regulatory guidance on terminations for conduct and performance and appeal rights can be found in parts 432 and 752, respectively.

6. Conversion to the Competitive Service (§ 362.306)

Several agencies asked OPM to modify the final rule to allow the use of agency-developed qualification standards for conversion to positions in the competitive service. We are not adopting this suggestion because we do not have the authority to do so under the Executive order, which requires use of OPM Qualification Standards. Recent Graduates must meet the OPM Qualification Standards for the position to which he or she will be converted. On the rare occasions where we have provided for agency-specific qualification standard, for a competitive service position, we are considering that to be an OPM Qualification Standard that agencies may use.

One agency asked OPM to specify time-in-grade (TIG) requirements for promotion at the time of conversion. We are not adopting this suggestion. Generally, excepted service employees are not subject to the TIG requirements of the competitive service. However, Recent Graduates are subject to the OPM Qualification Standards. This means that in order to promote a Recent Graduate, he or she would have to meet the specialized experience requirement of the applicable qualification standard, which is generally 1 year. The same requirements apply when converting the Recent Graduate to a competitive service position. For example, a GS–9 Recent Graduate would need 1 year of specialized experience at the GS–9 level at the time of conversion to be converted to a GS–11 position in the competitive service.

Several schools recommended OPM include a provision in the final rule to require conversion to the competitive service upon completion of the Recent Graduates Program. OPM is not adopting this suggestion because we believe conversion decisions should be based on the individual and the needs of the agency. We encourage agencies, however, to conduct sound workforce planning so that adequate conversion opportunities are available for Recent Graduates.

Recent Graduates must be rated under an agency's approved performance appraisal system as at least Fully Successful (or equivalent) to be eligible for conversion to the competitive service. One agency suggested OPM add requirements to clarify how performance will be evaluated when a

Recent Graduate moves to another agency. OPM is not adopting this suggestion, because no special rule applies to Recent Graduates. Rather, Recent Graduates are Federal employees subject to the performance management requirements specified in part 430 of 5 CFR.

D. Presidential Management Fellows Program (Part 362, Subpart D)

The proposed regulations set forth the rules governing the PMF Program in subpart D. OPM received several comments simply supporting or opposing the elimination of the school nomination process. A union urged OPM to retain the school nomination process. The union argues the nomination process is the key to maintaining the PMF as a rigorous, prestigious program. It suggested that OPM regulate standards for schools to apply when making nominations. It also cited anecdotal evidence that OPM's assessment process is more burdensome than the school nomination process. A good government group and an academic group commented in favor of the elimination of the nomination process. We agree with these commenters, rather than the union commenter. We do not believe that the school nomination process is critical any longer. It may be subject to inconsistent application and, for those schools not as familiar with how the PMF Program operates, has served as a barrier to application for qualified students, according to reports we have received from students at those institutions. Moreover, we have revamped our PMF assessment process to include, among other things, an interview process that has been professionally developed and validated by our industrial psychologists. Our new assessment process ensures that the PMF Program will remain a rigorous and prestigious program that uses a valid, professionally-developed selection process. Finally, as the academic commenter notes, the new eligibility rules for PMF allow an individual to participate up to 2 years after having obtained a degree. There would be substantial practical obstacles for schools to manage a nomination process that includes alumni, and for the alumni—who may now be very far away from campus—to participate in any such process.

1. Program Administration (§ 362.402)

One agency objected to subparagraph (d), which requires agencies to allow Fellows assigned to field locations to do a developmental rotation to agency headquarters and to allow Fellows to attend Federal Executive Board-sanctioned activities in their region. The agency asked OPM to modify the final rule by changing the word ''must'' to ''should'' or ''OPM highly recommends.'' The agency believes the current language places expectations on agencies that may be difficult to meet or inappropriate. We agree with the agency and modified the final rule to comport with this suggestion.

2. Announcement, Eligibility and Selection (§ 362.403)

Several agencies asked OPM to clarify the new eligibility criteria for PMFs. To clarify, individuals are eligible to apply to the PMF Program up to 2 years from the date of completion of the educational requirements for a professional or graduate degree. A PMF finalist may be appointed without regard to the time limit for application. For example, an individual could apply for the PMF Program a year and a half after completing his or her advanced degree. If the individual is selected as a finalist but does not receive an employment offer until two and a half years after completion of the degree, the individual may be appointed as a PMF. OPM is not establishing a limit on the number of times a graduate may apply to the PMF Program. However, a PMF finalist who chooses to reapply to a future announcement will be removed from the current finalist list and must successfully compete for placement on the new finalist list.

3. Appointment and Extension (§ 362.404)

Several agencies suggested OPM include a provision in the final rules allowing OPM to approve extensions of PMF appointments, not to exceed 1 year. OPM is not adopting this suggestion because the Executive order does not provide OPM the authority to do so. PMF appointments may only be extended up to a period of 120 days under the employing agencies' procedures. Agencies should only extend appointments under rare and unusual circumstances. The extension period should not be used as a standard practice to accommodate the processing of personnel actions.

4. Development, Evaluation, Promotion, and Certification (§ 362.405)

Most commenting agencies objected to the requirement that PMF mentors be in the Senior Executive Service (SES). OPM is persuaded by these comments. Talented mentors exist at the non-SES levels, and SES mentors may not be available in certain agency field locations. We adjusted the regulation to require a mentor to be a ''managerial employee outside the PMF's chain of command.''

A majority of agencies asked OPM to modify the provisions of paragraph (b)(6) that require agencies to provide PMFs to assist in the assessment process of new PMF applicants at the agency's expense. OPM agrees and has removed the provision requiring agencies to cover the expenses associated with providing PMF assessors.

5. Withdrawal and Readmission (§ 362.407)

One agency asked OPM if the last sentence of paragraph (a)(1) regarding reimbursement of the placement fee, was misplaced and should in fact be part of § 362.406, *Movement between agencies.* The agency is correct. We have modified the final rule by placing the sentence in § 362.406(d). The agency also asked OPM to clarify who would reimburse the original appointing agency, OPM or the gaining agency. The original appointing agency may request reimbursement from the gaining agency, not OPM.

Executive Order 13563 and Executive Order 12866

The Office of Management and Budget has reviewed this rule in accordance with E.O. 13563 and E.O. 12866.

Paperwork Reduction Act

This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

List of Subjects in 5 CFR Parts 213, 302, 315, 330, 334, 362, 531, 536, 537, 550, 575, and 890

Administrative practices and procedures, Colleges and universities, Employment, Government employees, Military personnel, Students, Veterans.

U.S. Office of Personnel Management.

John Berry,

Director.

Accordingly, the Office of Personnel Management is amending 5 CFR chapter I as follows:

PART 213—EXCEPTED SERVICE

■ 1. The authority citation for part 213 is revised to read as follows:

Authority: 5 U.S.C. 3161, 3301 and 3302; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218; E.O. 13562. Sec. 213.101 also issued under 5 U.S.C. 2103. Sec. 213.3102 also issued under 5 U.S.C. 3301, 3302, 3307, 8337(h), and 8456; 38 U.S.C. 4301 *et seq.;* and Pub. L. 105–339, 112 Stat. 3182–83.

Subpart A—General Provisions

■ 2. Revise § 213.102 to read as follows:

§ 213.102 Identification of positions in Schedule A, B, C, or D

(a) As provided in 5 U.S.C. 3302, the President may prescribe rules governing the competitive service. The rules shall provide, as nearly as conditions of good administration warrant, for—

(1) Necessary exceptions of positions from the competitive service; and

(2) Necessary exceptions from the provisions of sections 2951, 3304(a), 3321, 7202, and 7203 of title 5, U.S. Code.

(b) The President delegated authority to the Office of Personnel Management (OPM) in Civil Service Rule VI to except positions from the competitive service when OPM determines that:

(1) Appointments thereto through competitive examination are not practicable; or

(2) Recruitment from among students attending qualifying educational institutions or individuals who have recently completed qualifying educational programs can better be achieved by devising additional means for recruiting and assessing candidates that diverge from the processes generally applicable to the competitive service.

(3)(i) Upon determining that any position or group of positions, as defined in § 302.101(c), should be excepted indefinitely or temporarily from the competitive service, the Office of Personnel Management will authorize placement of the position or group of positions into Schedule A, B, C, or D, as applicable. Unless otherwise specified in a particular appointing authority, an agency may make Schedule A, B, C, or D appointments on either a permanent or nonpermanent basis, with any appropriate work schedule (*i.e.,* full-time, part-time, seasonal, on-call, or intermittent).

(ii) When OPM establishes eligibility requirements (*e.g.,* residence, family income) for appointment under particular Schedule A, B, or D exceptions, an individual's eligibility for appointment must be determined before appointment and without regard to any conditions that will result from the appointment.

(c) For purposes of making any such determinations, *positions* includes:

(1) Those that are intended to be removed indefinitely from the competitive service because the nature of the position itself precludes it from being in the competitive service (*e.g.,* because it is impracticable to examine for the knowledge, skills, and abilities required for the job); and

(2) Those that are intended to be removed temporarily from the competitive service to allow for targeted recruiting and hiring from among a particular class of persons, as defined by the Office of Personnel Management, with the opportunity for the persons selected for those positions to convert to the competitive service at a later date.

■ 3. In § 213.103, revise the section heading and paragraph (a) to read as follows:

§ 213.103 Publication of excepted appointing authorities in Schedules A, B, C, and D.

(a) Schedule A, B, C, and D appointing authorities available for use by all agencies will be published as regulations in the **Federal Register** and the Code of Federal Regulations.

* * * * *

■ 4. In § 213.104, revise the section heading, paragraph (a) introductory text, and paragraphs (a)(1), (b)(1), (b)(2), and (b)(3)(ii) to read as follows:

§ 213.104 Special provisions for temporary, time-limited, intermittent, or seasonal appointments in Schedule A, B, C, or D.

(a) When OPM specifies that appointments under a particular Schedule A, B, C, or D authority must be temporary, intermittent, or seasonal, or when agencies elect to make temporary, intermittent, or seasonal appointments in Schedule A, B, C, or D, those terms have the following meaning:

(1) *Temporary appointments,* unless otherwise specified in a particular Schedule A, B, C, or D exception, are made for a specified period not to exceed 1 year and are subject to the time limits in paragraph (b) of this section. Time-limited appointments made for more than 1 year are not considered to be temporary appointments, and are not subject to these time limits.

* * * * *

(b) * * *

(1) *Service limits.* Agencies may make temporary appointments for a period not to exceed 1 year, unless the applicable Schedule A, B, C, or D authority specifies a shorter period. Except as provided in paragraph (b)(3) of this section, agencies may extend temporary appointments for no more than 1 additional year (24 months of total service). Appointment to a successor position (*i.e.,* a position that replaces and absorbs the original position) is considered to be an extension of the original appointment. Appointment to a position involving the same basic duties, in the same major subdivision of the agency, and in the same local commuting area is also considered to be an extension of the original appointment.

(2) *Restrictions on refilling positions under temporary appointments.* Except as provided in paragraph (b)(3) of this section, an agency may not fill any position (or its successor) by a temporary appointment in Schedule A, B, C, or D if that position had previously been filled by temporary appointment(s) in either the competitive or excepted service for an aggregate of 2 years, or 24 months, within the preceding 3-year period. This limitation does not apply to programs established to provide for systematic exchange between a Federal agency and non-Federal organizations.

(3) * * *

(ii) Positions are filled under an authority established for the purpose of enabling the appointees to continue or enhance their education, or to meet academic or professional qualification requirements. These include the authorities set out in paragraphs (r) and (s) of § 213.3102 and paragraphs (a), (b), and (c) of § 213.3402, and authorities granted to individual agencies for use in connection with internship, fellowship, residency, or student programs.

* * * * *

Subpart C—Excepted Schedules

■ 5. In § 213.3102, remove and reserve paragraphs (ii) and (jj).

§ 213.3102 Entire executive civil service.

* * * * *

(ii) [Reserved]

(jj) [Reserved]

* * * * *

■ 6. In § 213.3202, remove and reserve paragraphs (a), (b), and (o).

§ 213.3202 Entire executive civil service.

(a) [Reserved]

(b) [Reserved]

* * * * *

(o) [Reserved]

* * * * *

■ 7. After § 213.3302, add a new undesignated center heading and § 213.3401 and § 213.3402 to read as follows:

Schedule D

§ 213.3401 Positions other than those of a confidential or policy determining character for which the competitive service requirements make impracticable the adequate recruitment of sufficient numbers of students attending qualifying educational institutions or individuals who have recently completed qualifying educational programs.

As authorized by OPM, agencies may make appointments under this section to positions other than those of a confidential or policy-determining character for which the competitive service requirements make impracticable the adequate recruitment and selection of sufficient numbers of students attending qualifying educational institutions or individuals who have recently completed qualifying educational programs. These positions, which may be filled in the excepted service to enable more effective recruitment from all segments of society by using means of recruiting and assessing candidates that diverge from the rules generally applicable to the competitive service, constitute Schedule D Pathways Programs. Appointments under this authority are subject to the basic qualification standards established by the Office of Personnel Management for the occupation and grade level unless otherwise stated.

§ 213.3402 Entire executive civil service; Pathways Programs.

(a) *Internship Program; Positions in the Internship Program.* Agencies may make initial appointments of Interns under this authority at any grade level, depending on the candidates' qualifications. Appointments must be made in accordance with the provisions of subpart B of part 362 of this chapter.

(b) *Recent Graduates Program; Positions in the Recent Graduates Program.* (1) Agencies may make initial appointments of Recent Graduates at any grade level, not to exceed GS–09 (or equivalent level under another pay and classification system, including the Federal Wage System (FWS)), depending on the candidates' qualifications, and the position's requirements except that:

(i) Initial appointments to positions for science, technology, engineering, or mathematics (STEM) occupations may be made at the GS–11 level, if the candidate possesses a Ph.D. or equivalent degree directly related to the STEM position the agency is seeking to fill.

(ii) Initial appointments to scientific and professional research positions at the GS–11 level for which the classification and qualification criteria for research positions apply, if the candidate possesses a master's degree or equivalent graduate degree directly related to the position the agency is seeking to fill.

(iii) Initial appointments to scientific and professional research positions at the GS–12 level for which the classification and qualification criteria for research positions apply, if the candidate possesses a Ph.D. or equivalent degree directly related to the position the agency is seeking to fill.

(2) Appointments must be made in accordance with the provisions of subpart C of part 362 of this chapter.

(c) *Presidential Management Fellows Program.* Positions in the Presidential Management Fellows Program. Appointments under this authority may not exceed 2 years except as provided in subpart D of part 362 of this chapter. Agencies may make initial appointments of Fellows at the GS–09, GS–11, or GS–12 level (or equivalent under another pay and classification system such as the FWS), depending on the candidates' qualifications and the positions' requirements. Appointments must be made in accordance with the provisions of subpart D of part 362 of this chapter.

PART 302—EMPLOYMENT IN THE EXCEPTED SERVICE

■ 8. The authority citation for part 302 continues to read as follows:

Authority: 5 U.S.C. 1302, 3301, 3302, 8151, E.O. 10577 (3 CFR 1954–1958 Comp., p. 218); § 302.105 also issued under 5 U.S.C. 1104, Pub. L. 95–454, sec. 3(5); § 302.501 also issued under 5 U.S.C. 7701 *et seq.*

■ 9. In § 302.101, remove paragraph (c)(8) and redesignate paragraphs (c)(9) through (11) as paragraphs (c)(8) through (10), respectively.

PART 315—CAREER AND CAREER–CONDITIONAL EMPLOYMENT

■ 10. The authority citation for part 315 is revised to read as follows:

Authority: 5 U.S.C. 1302, 3301, and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp. p. 218, unless otherwise noted; and E.O. 13562. Secs. 315.601 and 315.609 also issued under 22 U.S.C. 3651 and 3652. Secs. 315.602 and 315.604 also issued under 5 U.S.C. 1104. Sec. 315.603 also issued under 5 U.S.C. 8151. Sec. 315.605 also issued under E.O. 12034, 3 CFR, 1978 Comp. p. 111. Sec. 315.606 also issued under E.O. 11219, 3 CFR, 1964–1965 Comp. p. 303. Sec. 315.607 also issued under 22 U.S.C. 2506. Sec. 315.608 also issued under E.O. 12721, 3 CFR, 1990 Comp. p. 293. Sec. 315.610 also issued under 5 U.S.C. 3304(c). Sec. 315.611 also issued under 5 U.S.C. 3304(f). Sec. 315.612 also issued under E.O. 13473. Sec. 315.710 also issued under E.O. 12596, 3 CFR, 1987 Comp. p. 229. Subpart I also issued under 5 U.S.C. 3321, E.O. 12107, 3 CFR, 1978 Comp. p. 264.

Subpart B—The Career-Conditional Employment System

■ 11. In § 315.201, revise paragraphs (b)(1)(ix), (b)(1)(xiii), and (b)(1)(xix) and add paragraphs (b)(1)(xx), (b)(1)(xxi), and (b)(1)(xxii) to read as follows:

§ 315.201 Service requirement for career tenure.

* * * * *

(b) * * *

(1) * * *

(ix) The date of nontemporary excepted appointment under § 213.3202(b) of this chapter (the former Student Career Experience Program) as in effect immediately before the effective date of the regulations removing that paragraph, provided the student's appointment is converted to career or career-conditional appointment under Executive Order 12015, with or without an intervening term appointment, and without a break in service of one day.

* * * * *

(xiii) The date of appointment as a Participant in the Presidential Management Fellows Program under the provisions of Executive Order 13318, provided the employee's appointment is converted without a break in service to career or career-conditional appointment under § 315.708 as in effect immediately before the effective date of the regulations that removed and reserved that section;

* * * * *

(xix) Appointment as a career intern under Schedule B, § 213.3202(o) of this chapter, provided the employee's appointment is converted to career or career-conditional appointment under § 315.712 as in effect immediately before the effective date of the regulations that removed and reserved that section;

(xx) The date of appointment as a Pathways Participant in the Internship Program under Schedule D, § 213.3402(a) of this chapter, provided the employee's appointment is converted to career or career-conditional appointment under § 315.713(a), with or without an intervening term appointment, and without a break in service of one day;

(xxi) The date of appointment as a Pathways Participant in the Recent Graduates Program under Schedule D, § 213.3402(b) of this chapter, provided the employee's appointment is converted to career or career-conditional appointment under § 315.713(b), with or

without an intervening term appointment, and without a break in service of one day; and

(xxii) The date of appointment as a Pathways Participant in the Presidential Management Fellows Program under Schedule D, § 213.3402(c) of this chapter, provided the employee's appointment is converted to career or career-conditional appointment under § 315.713(c), with or without an intervening term appointment, and without a break in service of one day.

* * * * *

Subpart G—Conversion to Career or Career-Conditional Employment From Other Types of Employment

§ 315.708 [Removed and Reserved]

■ 12a. Remove and reserve § 315.708.

§ 315.712 [Removed and Reserved]

■ 12b. Remove and reserve § 315.712.

■ 12c. Add a new § 315.713 to subpart G to read as follows:

§ 315.713 Conversion based on service in a Pathways Program under part 362 of this chapter.

(a) *Agency authority.* An agency may convert to a career or career-conditional employment in the competitive service, without further competition, the following Pathways Participants:

(1) An Intern who has satisfactorily completed the Internship Program and meets all eligibility requirements for conversion under subpart B of part 362 of this chapter;

(2) A Recent Graduate who has satisfactorily completed the Recent Graduates Program and meets all eligibility requirements for conversion under subpart C of part 362 of this chapter; and

(3) A Presidential Management Fellow who has satisfactorily completed the Fellows Program and meets all eligibility requirements for conversion under subpart D of part 362 of this chapter.

(b) *Tenure on conversion.* An employee whose appointment is converted to career or career-conditional employment under this section becomes:

(1) A career-conditional employee except as provided in paragraph (b)(2) of this section;

(2) A career employee when he or she has completed the service requirement for career tenure or is excepted from it by § 315.201(c).

(c) *Acquisition of competitive status.* A Pathways Participant converted to career or career-conditional employment in the competitive service under this section acquires competitive status upon completion of probation.

PART 330—RECRUITMENT, SELECTION, AND PLACEMENT (GENERAL)

■ 13. The authority citation for part 330 continues to read as follows:

Authority: 5 U.S.C. 1104, 1302, 3301, 3302, 3304, and 3330; E.O. 10577, 3 CFR, 1954–58 Comp., p. 218; Section 330.103 also issued under 5 U.S.C. 3327; Subpart B also issued under 5 U.S.C. 3315 and 8151; Section 330.401 also issued under 5 U.S.C. 3310; Subparts F and G also issued under Presidential Memorandum on Career Transition Assistance for Federal Employees, September 12, 1995; Subpart G also issued under 5 U.S.C. 8337(h) and 8456(b).

■ 14. In § 330.211, revise paragraph (f)(3) to read as follows:

§ 330.211 Exceptions to RPL placement priority.

* * * * *

(f) * * *

(3) An excepted service appointment under part 213 of this chapter;

* * * * *

■ 15. In § 330.609, revise paragraph (e)(3) to read as follows:

§ 330.609 Exceptions to CTAP selection priority.

* * * * *

(e) * * *

(3) Make an excepted service appointment under part 213 of this chapter;

* * * * *

■ 16. In § 330.707, revise paragraph (h)(3) to read as follows:

§ 330.707 Exceptions to ICTAP selection priority.

* * * * *

(h) * * *

(3) An excepted service appointment under part 213 of this chapter;

* * * * *

PART 334—TEMPORARY ASSIGNMENTS UNDER THE INTERGOVERNMENTAL PERSONNEL ACT (IPA)

■ 17. The authority citation for part 334 continues to read as follows:

Authority: 5 U.S.C. 3376; E.O. 11589, 3 CFR 557 (1971–1975).

■ 18. In § 334.102 revise the definition of *employee* to read as follows:

§ 334.102 Definitions.

* * * * *

Employee, for purposes of participation in this Program, means an individual serving in a Federal agency under a career or career-conditional appointment, including a career appointee in the Senior Executive Service, an individual under an appointment of equivalent tenure in an excepted service position, or an individual employed for at least 90 days in a career position with a State, local, or Indian tribal government, institution of higher education, or other eligible organization;

* * * * *

■ 19. Revise part 362 to read as follows:

PART 362—PATHWAYS PROGRAMS

Subpart A—General Provisions

Sec.
362.101 Program administration.
362.102 Definitions.
362.103 Authority.
362.104 Agency requirements.
362.105 Filling positions.
362.106 Participant Agreement.
362.107 Conversion to the competitive service.
362.108 Program oversight.
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362.110 Transition.

Subpart B—Internship Program

362.201 Agency authority.
362.202 Definitions.
362.203 Filling positions.
362.204 Conversion to the competitive service.
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Subpart C—Recent Graduates Program

362.301 Program administration.
362.302 Eligibility.
362.303 Filling positions.
362.304 Movement between agencies.
362.305 Conversion to the competitive service.
362.306 Reduction in force and termination.

Subpart D—Presidential Management Fellows Program

362.401 Definitions.
362.402 Program administration.
362.403 Announcement, eligibility, and selection.
362.404 Appointment and extension.
362.405 Development, evaluation, promotion, and certification.
362.406 Movement between agencies.
362.407 Withdrawal and readmission.
362.408 Termination and reduction in force.
362.409 Conversion to the competitive service.

Authority: E.O. 13562, 75 FR 82585. 3 CFR, 2010 Comp., p. 291

Subpart A—General Provisions

§ 362.101 Program administration.

(a) The Pathways Programs authorized under Executive Order 13562 consist of the following three Programs:

(1) The Internship Program;

(2) The Recent Graduates Program; and

(3) The Presidential Management Fellows (PMF) Program.

(b) An agency may rename the Programs specified in paragraphs (a)(1) through (3) of this section, provided that the agency-specific name includes the Pathways Program name identified in paragraph (a) of this section, *e.g.,* Treasury Internship Program.

(c) Agencies must provide for equal employment opportunity in the Pathways Programs without regard to race, ethnicity, color, religion, sex (including pregnancy and gender identity), national origin, age, disability, sexual orientation, genetic information, or any other non-merit-based factor.

§ 362.102 Definitions.

For the purposes of this part:

Advanced degree means a professional or graduate degree, *e.g.* master's, Ph.D., J.D.

Agency means an agency as defined in 5 U.S.C. 105, and the Government Printing Office.

Certificate program means post-secondary education, in a qualifying educational institution, equivalent to at least one academic year of full-time study that is part of an accredited college-level, technical, trade, vocational, or business school curriculum.

Director means the Director of OPM or his or her designee.

OPM means the Office of Personnel Management.

Participant Agreement means a written agreement between the agency and each Pathways Participant.

Program Participant or Pathways Participant means any individual appointed under a Pathways Program.

Qualifying educational institution means—

(1) A public high school whose curriculum has been approved by a State or local governing body, a private school that provides secondary education as determined under State law, or a homeschool that is allowed to operate in a State; and

(2) Any of the following educational institutions or curricula that have been accredited by an accrediting body recognized by the Secretary of the U.S. Department of Education:

(i) A technical or vocational school;

(ii) A 2-year or 4-year college or university;

(iii) A graduate or professional school (*e.g.,* law school, medical school); or

(iv) A post-secondary homeschool curriculum.

§ 362.103 Authority.

An agency may make an appointment under this part to a position defined in § 213.3402 of this chapter, provided a Memorandum of Understanding between the head of the agency or his or her designee and OPM is in effect.

§ 362.104 Agency requirements.

(a) *Memorandum of Understanding.* In order to make any appointment under a Pathways authority, a Memorandum of Understanding (Pathways MOU) must be in effect between the head of an agency, or his or her designee, and OPM for the administration and use of Pathways Programs, to be re-executed no less frequently than every 2 years.

(b) The Director may revoke an agency's Pathways MOU when agency use of these Programs is inconsistent with Executive Order 13562, this part, or the Pathways MOU.

(c) The Pathways MOU must:

(1) Include information about any agency-specific program labels that will be used, subject to the Federal naming conventions identified in § 362.101 (*e.g.,* OPM Internship Program);

(2) State the delegations of authority for the agency's use of the Pathways Programs (*e.g.,* department-wide vs. bureaus or components);

(3) Include any implementing policy or guidance that the agency determines would facilitate successful implementation and administration for each Pathways Program;

(4) Prescribe criteria and procedures for agency-approved extensions for Recent Graduates and PMFs, not to exceed 120 days. Extension criteria should be limited to circumstances that would render the agency's compliance with the regulations impracticable or impossible;

(5) Describe how the agency will design, implement, and document formal training and/or development, as well as the type and duration of assignments, and necessary exceptions for short term temporary work, such as summer jobs;

(6) Include a commitment from the agency to:

(i) Provide to OPM any information it requests on the agency's Pathways Programs;

(ii) Adhere to any caps on the Pathways Programs imposed by the Director;

(iii) Provide information to OPM about opportunities for individuals interested in participating in the Pathways Programs, as required by this part;

(iv) Ensure adherence to the requirements for accepting applications, assessing applicants, rating and ranking qualified candidates, and affording veterans' preference in accordance with the provisions of part 302; and

(v) Provide a meaningful on-boarding process for each Pathways Program;

(7) Identify the agency's Pathways Programs Officer (PPO), who:

(i) Must be in a position at the agency's headquarters level, or at the headquarters level of a departmental component, in a position at or higher than grade 12 of the General Schedule (GS) (or the equivalent under the Federal Wage System (FWS) or another pay and classification system);

(ii) Is responsible for administering the agency's Pathways Programs, including coordinating the recruitment and on-boarding process for Pathways Programs Participants, and coordinating the agency's Pathways Programs plan with agency stakeholders and other hiring plans (*e.g.,* merit promotion plans, plans for hiring people with disabilities);

(iii) Serves as a liaison with OPM by providing updates on the agency's implementation of its Pathways Programs, clarifying technical or programmatic issues, sharing agency best practices, and other similar duties; and

(iv) Reports to OPM on the agency's implementation of its Pathways Programs and individuals hired under these Programs, in conjunction with the agency's Pathways MOU; and

(8) Identify the agency's PMF coordinator responsible for administering the agency PMF Program and serving as a liaison with OPM.

§ 362.105 Filling positions.

(a) *Workforce Planning.* Before filling any positions under these Programs, agencies should include measures in their workforce planning to ensure that an adequate number of permanent positions will be available to convert Pathways Participants who successfully complete their Programs.

(b) *Announcements.* When an agency accepts applications from individuals outside its own workforce, it must provide OPM information concerning Pathways Programs job opportunities as provided in each Pathways Program. For the purposes of this paragraph, ''agency'' means an Executive agency as defined in 5 U.S.C. 105 and the Government Printing Office. An Executive department may treat each of its bureaus or components (first major subdivision that is separately organized and clearly distinguished from other bureaus or components in work function and operation) as a separate agency or as part of one agency, but

must do so consistent with its Delegated Examining Agreement.

(c) *Appointments.* (1) Agencies must fill positions under the Pathways Programs using the excepted service appointing authority provided by § 213.3402 (a), (b), or (c) of this chapter, as applicable.

(2) Agencies must follow the procedures of part 302 of this chapter when filling a position under a Pathways Program.

(3) Appointments are subject to all the requirements and conditions governing term, career, or career-conditional employment, including investigation to establish an appointee's qualifications and suitability.

(d) *Eligibility.* Except as set forth in this section, eligibility requirements for appointment under a Pathways Program are specified in each Pathways Program.

(e) *Citizenship.* (1) An agency may appoint a non-citizen provided that:

(i) The Pathways Participant is lawfully admitted to the United States as a permanent resident or is otherwise authorized to be employed; and

(ii) The agency is authorized to pay aliens under the annual Appropriations Act ban and any agency-specific enabling and appropriation statutes.

(2) A Pathways Participant must be a United States citizen to be eligible for noncompetitive conversion to the competitive service.

(f) *Employment of relatives.* In accordance with part 310 of this chapter, a Pathways Participant may work in the same agency with a relative when there is no direct reporting relationship and the relative is not in a position to influence or control the Participant's appointment, employment, promotion or advancement within the agency.

(g) *Length of Appointments.* Except as provided in subpart B, Recent Graduate and PMF appointments under this authority may not exceed 2 years plus any agency-approved extension of up to 120 days.

(h) *Terminations.* An agency may terminate a Pathways Participant for reasons including misconduct, poor performance, or suitability under the provisions of this chapter.

(i) *Performance and progress evaluation.* Each Participant must be placed on a performance plan, as prescribed by part 430 of this chapter or other applicable law or regulation, establishing performance elements and standards that are directly related to acquiring and demonstrating the various leadership, technical, and/or general competencies expected of the Participant, as well as the elements and standards established for the duties assigned.

(j) *Compensation.* The rules for setting pay upon the initial appointment of a Participant are governed by the pay administration rules of the pay system or pay plan of the Participant's position under the Pathways program. In determining the Participant's compensation, agencies may also use any applicable pay flexibilities available under that pay system or pay plan (*e.g.,* recruitment, relocation, and retention incentives under part 575 of this chapter; student loan repayments under part 537; and, for General Schedule positions, special rates under part 530, subpart C, and the superior qualifications and special needs pay setting authority and the maximum payable rate rule under part 531, subpart B).

§ 362.106 Participant Agreement.

Agencies must execute a written Participant Agreement with each Pathways Participant that clearly identifies expectations, including but not limited to:

(a) A general description of duties;

(b) Work schedules;

(c) The length of the appointment and termination date;

(d) Mentorship opportunities;

(e) Training requirements as applicable;

(f) Evaluation procedures that will be used for the Participant;

(g) Requirements for continuation and successful completion of the Program; and

(h) Minimum eligibility requirements for noncompetitive conversion to term or permanent competitive service employment according to the requirements of the applicable Pathways Program.

§ 362.107 Conversion to the competitive service.

(a) Subject to any limits on conversion imposed by the Director, and in accordance with the provisions of each Pathways Program, an agency may noncompetitively convert an eligible Pathways Participant to a term or permanent competitive service position.

(b) A Pathways Participant who is noncompetitively converted to a competitive service term appointment may be subsequently converted noncompetitively to a permanent competitive service position.

(c) *Noncompetitive conversion.* (1) An Intern may be converted to a position within the employing agency or any other agency within the Federal Government.

(2) A Recent Graduate or Presidential Management Fellow may be converted within the employing agency. Agencies may not convert Recent Graduates or Presidential Management Fellows from other agencies.

(d) The provisions of the career transition assistance programs in subparts B, F and G of part 330 of this chapter do not apply to conversions made under this part.

(e) Time spent serving as a Pathways Participant counts towards career tenure when the individual is noncompetitively converted to a permanent position in the competitive service upon completion of the Program, with or without an intervening term appointment, and without a break in service of one day.

(f) Though Pathways Participants are eligible for noncompetitive conversion to the competitive service upon successful completion of their Program and any other applicable conversion requirements, service in a Pathways Program confers no right to further employment in either the competitive or excepted service. An agency wishing to convert a Pathways Participant must therefore execute the required actions to do so.

§ 362.108 Program oversight.

(a) The Director may establish caps on the number of Pathways Participants who may be appointed or converted in any Pathways Program within a specific agency or throughout the Federal Government.

(b) The Director may establish such caps based on agency or Governmentwide use of the Pathways Programs, input from the Executive agencies, and consideration of the following:

(1) Agency MOU compliance;

(2) Agency approach to entry-level hiring;

(3) Agency engagement in sound workforce planning to ensure that an adequate number of permanent positions will be available to which Pathways Participants who successfully complete their Programs can be converted;

(4) Agency record in using the Pathways Programs as a supplement to competitive examining, rather than as a substitute for it;

(5) Agency record of publicizing their positions in the Pathways Programs and recruiting and selecting from a broad array of sources; and

(6) Any other information the Director deems relevant.

(c) In the event the Director determines that any caps would be appropriate, OPM will publish notice of such caps in a manner chosen by the Director.

§ 362.109 Reporting requirements.

Agencies must provide information requested by OPM regarding workforce planning strategies that includes:

(a) Information on the entry-level occupations targeted for filling positions under this part in the coming year;

(b) The percentage of overall hiring expected in the coming year under the Internship, Recent Graduates, and Presidential Management Fellows Programs; and

(c) For the previous year:

(1) The number of individuals initially appointed under each Pathways Program;

(2) The percentage of the agency's overall hires made from each Pathways Program;

(3) The number of Pathways Participants, per Program, converted to the competitive service; and

(4) The number of Pathways Participants, per Program, who were separated.

§ 362.110 Transition.

OPM will provide written guidance for the orderly transition of employees currently appointed as students under the Student Educational Employment Program and current PMFs to the applicable Pathways Program and may revise that guidance as necessary.

Subpart B—Internship Program

§ 362.201 Agency authority.

The Internship Program provides students in high schools, colleges, trades schools and other qualifying educational institutions, as defined in § 362.102 of this part, the opportunity to explore Federal careers as paid employees while completing their education. Students appointed under this authority are referred to as Interns.

§ 362.202 Definitions.

In this subpart:

Student means an individual accepted for enrollment or enrolled and seeking a degree (diploma, certificate, etc.) in a qualifying educational institution, on a full or half-time basis (as defined by the institution in which the student is enrolled), including awardees of the Harry S. Truman Foundation Scholarship Program under Public Law 93–842. Students need not be in actual physical attendance, so long as all other requirements are met. An individual who needs to complete less than the equivalent of half an academic/vocational or technical course-load immediately prior to graduating is still considered a student for purposes of this Program.

§ 362.203 Filling positions.

(a) *Announcement.* (1) When an agency accepts applications from individuals outside its own workforce, it must provide OPM information concerning opportunities to participate in the agency's Internship Program. For the purposes of this paragraph (a), ''agency'' means an Executive agency as defined in 5 U.S.C. 105 and the Government Printing Office. An Executive department may treat each of its bureaus or components (first major subdivision that is separately organized and clearly distinguished from other bureaus or components in work function and operation) as a separate agency or as part of one agency, but must do so consistent with its Delegated Examining Agreement. The information must include:

(i) Position title, series and grade;

(ii) Geographic location of the position, and

(iii) How to apply. A public source (*e.g.,* a link to the agency's Web site with information on how to apply) for interested individuals to seek further information about how to apply for Internship opportunities; and

(iv) Any other information OPM considers appropriate.

(2) OPM will publish information on Internship opportunities in such form as the Director may determine.

(b) *Eligibility.* Except as provided in paragraph (h) of this section, Interns must meet the definition of *student* in § 362.202 throughout the duration of their appointment.

(c) *Qualifications.* Individuals may be evaluated against either agency-developed standards or the OPM Qualification Standard for the position being filled.

(d) *Appointments.* (1) An agency may make Intern appointments, pursuant to its Pathways MOU, using the Schedule D excepted service appointing authority provided in § 213.3402(a) of this chapter.

(2) Appointments may be made to any position for which the individual is qualified. The duties of the position to which the individual is appointed should be related to either the Intern's academic or career goals.

(3) An agency may:

(i) Appoint an Intern for an initial period expected to last more than 1 year. Intern appointments are not required to have an end date. However, agencies are required to specify an end date of the appointment in the Participant Agreement with the Intern; or

(ii) Appoint an Intern on a temporary basis, not to exceed 1 year, to complete temporary projects, to perform labor-intensive tasks not requiring subject-matter expertise, or to fill traditional summer jobs. The agency may extend these temporary appointments as provided in part 213 of this chapter.

(e) *Promotion.* An agency may promote any Intern who meets the qualification requirements for the position. This provision does not confer entitlement to promotion.

(f) *Classification.* (1) Intern positions under the General Schedule or appropriate pay plan must be classified to the –99 series of the appropriate occupational group.

(2) Intern positions under the Federal Wage System must be classified to the –01 series of the appropriate occupational group.

(g) *Schedules.* There are no limitations on the number of hours an Intern can work per week (so long as any applicable laws and regulations governing overtime and hours of work are adhered to). Agencies and students should agree on a formally-arranged schedule of school and work so that:

(1) Work responsibilities do not interfere with academic schedule;

(2) Completion of the educational program (awarding of diploma/certificate/degree) and the Internship Program is accomplished in a reasonable and appropriate timeframe;

(3) The agency is informed of and prepared for the student's periods of employment; and

(4) Requirements for noncompetitive conversion to a term or permanent position in the competitive service are understood by all parties.

(h) *Breaks in program.* A break in program is defined as a period of time when an Intern is working but is unable to go to school, or is neither attending classes nor working at the agency. An agency may use its discretion in either approving or denying a request for a break in program.

§ 362.204 Conversion to the competitive service.

(a) An agency may noncompetitively convert an Intern who is a U.S. citizen, to a term or permanent appointment in the competitive service.

(b) To be eligible for conversion, the Intern must have:

(1) Completed at least 640 hours of work experience acquired through the Internship Program, except as provided in paragraphs (c) and (d) of this section, while enrolled as a full-time or part-time, degree- or certificate-seeking student;

(2) Completed a course of academic study, within the 120-day period preceding the appointment, at a qualifying educational institution

conferring a diploma, certificate, or degree;

(3) Received a favorable recommendation for appointment by an official of the agency or agencies in which the Intern served;

(4) Met the qualification standards for the position to which the Intern will be converted; and

(5) Met agency-specific requirements as specified in the agency's Participant Agreement with the Intern.

(c)(1) An agency may evaluate, consider, and grant credit for up to one-half (320 hours) of the 640-hour service requirement in paragraph (b)(1) of this section for comparable non-Federal internship experience in a field or functional area related to the student's target position and acquired while the student:

(i) Worked in, but not for, a Federal agency, pursuant to a formal internship agreement, comparable to the Internship Program under this subpart, between the agency and an accredited academic institution;

(ii) Worked in, but not for, a Federal agency, pursuant to a written contract with a third-party internship provider officially established to provide internship experiences to students that are comparable to the Internship Program under this subpart; or

(iii) Served as an active duty member of the armed forces (including the National Guard and Reserves), as defined in 5 U.S.C. 2101, provided the veteran's discharge or release is under honorable conditions.

(2) Student volunteer service under part 308 of this chapter and other Federal programs designed to give internship experience to students (*e.g.,* fellowships and similar programs), may be evaluated, considered, and credited under this section when the agency determines the experience is comparable to experience gained in the Internship Program.

(d) An agency may waive up to one-half (*i.e.,* 320 hours) of the 640-hour minimum service requirement in paragraph (b)(1) of this section when an Intern completes 320 hours of career-related work experience under an Internship Program appointment and demonstrates high potential by outstanding academic achievement and exceptional job performance. For purposes of this paragraph:

(1) *Outstanding academic achievement* means an overall grade point average of 3.5 or better, on a 4.0 scale; standing in the top 10 percent of the student's graduating class; and/or induction into a nationally-recognized scholastic honor society.

(2) *Exceptional job performance* means a formal evaluation conducted by the student's Internship supervisor(s), consistent with the applicable performance appraisal program that results in a rating of record (or summary rating) of higher than Fully Successful or equivalent.

(e) An agency may not grant a credit or waiver (or a combination of a credit and waiver) totaling more than 320 hours of the 640-hour service requirement in paragraph (b)(1) of this section.

§ 362.205 Reduction in force (RIF) and termination.

(a) *Reduction in force.* Interns are covered by part 351 of this chapter for purposes of RIF.

(1) *Tenure Groups.* (i) An Intern serving under an appointment for an initial period expected to last more than 1 year is in excepted service Tenure Group II.

(ii) A temporary Intern, serving under an appointment not to exceed 1 year, who has not completed 1 year of service, is in excepted service Tenure Group 0.

(iii) A temporary Intern serving under an appointment not to exceed 1 year, who has completed 1 year of current, continuous service, is in excepted service Tenure Group III.

(2) [Reserved]

(b) *Termination.* As a condition of employment, an Intern appointment expires:

(1) 120 days after completion of the designated academic course of study, unless the Participant is selected for noncompetitive conversion under § 362.204, or

(2) Upon expiration of the temporary Internship appointment.

Subpart C—Recent Graduates Program

§ 362.301 Program administration.

The Recent Graduates Program provides an entry-level developmental experience designed to lead to a civil service career in the Federal Government after successfully completing 1 year under the Program, unless the training requirements of the position warrant a longer and more structured training program. Employment under the Recent Graduates Program may not exceed 2 years plus any agency approved extension of up to an additional 120 days. Individuals appointed under this authority are referred to as Recent Graduates. An agency wishing to participate in the Recent Graduates Program must:

(a) Identify in the MOU the duration of its Recent Graduates Program, including any criteria used to determine the need for a longer and more structured training program that exceeds 1 year;

(b) Ensure, within 90 days of appointment, that each Recent Graduate is assigned a mentor who is an employee outside the Recent Graduates' chain of command;

(c) Ensure, within 45 days of appointment, that each Recent Graduate has an Individual Development Plan (IDP) that is approved by his or her supervisor; and

(d) Provide at least 40 hours of formal interactive training per year that advances the goals and competencies outlined in each Recent Graduate's IDP. Mandatory annual training, such as information security and ethics training, does not count towards the 40-hour requirement.

§ 362.302 Eligibility.

(a) A Recent Graduate is an individual who obtained a qualifying associates, bachelors, master's, professional, doctorate, vocational or technical degree or certificate from a qualifying educational institution, within the previous 2 years or other applicable period provided below.

(b)(1) Except as provided in paragraph (b)(2) of this section, an individual may apply for a position in the Recent Graduates Program only if the individual's application is received not later than 2 years after the date the individual completed all requirements of an academic course of study leading to a qualifying associates, bachelor's, master's, professional, doctorate, vocational or technical degree or certificate from a qualifying educational institution.

(2) A veteran, as defined in 5 U.S.C. 2108, who, due to a military service obligation, was precluded from applying to the Recent Graduates Program during any portion of the 2-year eligibility period described in paragraph (b)(1) of this section shall have a full 2-year period of eligibility upon his or her release or discharge from active duty. In no event, however, may the individual's eligibility period extend beyond 6 years from the date on which the individual completed the requirements of an academic course of study.

§ 362.303 Filling positions.

(a) *Announcement.* (1) When an agency accepts applications from individuals outside its own workforce, it must provide OPM information concerning opportunities to participate in the agency's Recent Graduates

Program. For the purposes of this paragraph, ''agency'' means an Executive agency as defined in 5 U.S.C. 105 and the Government Printing Office. An Executive department may treat each of its bureaus or components (first major subdivision that is separately organized and clearly distinguished from other bureaus or components in work function and operation) as a separate agency or as part of one agency, but must do so consistent with its Delegated Examining Agreement. The information must include:

(i) Position title, series and grade;

(ii) Geographic location of the position;

(iii) How to apply. A public source (*e.g.,* a link to the agency's Web site with information on how to apply for interested individuals to seek further information about how to apply); and

(iv) Any other information OPM considers appropriate.

(2) OPM will publish information on Recent Graduate opportunities in such form as the Director may determine.

(b) *Appointments.* (1) An agency may make appointments to the Recent Graduates Program, pursuant to a Pathways MOU executed with the OPM, under Schedule D of the excepted service in accordance with part 302 of this chapter.

(2) An agency must appoint a Recent Graduate using the excepted service appointing authority provided by § 213.3402(b) of this chapter.

(3)(i) An agency may make an initial appointment of a Recent Graduate to any position filled under this authority for which the Recent Graduate qualifies, up to the GS–09 level (or equivalent under another pay and classification system, such as the Federal Wage System), except as provided in paragraphs (b)(3)(ii) through (iv) of this section.

(ii) Initial appointments to positions for science, technology, engineering, or mathematics (STEM) occupations may be made at the GS–11 level, if the candidate possesses a Ph.D. or equivalent degree directly related to the STEM position the agency is seeking to fill.

(iii) Initial appointments to scientific and professional research positions at the GS–11 level for which the classification and qualification criteria for research positions apply, if the candidate possesses a master's degree or equivalent graduate degree directly related to the position the agency is seeking to fill.

(iv) Initial appointments to scientific and professional research positions at the GS–12 level for which the classification and qualification criteria for research positions apply, if the candidate possesses a Ph.D. or equivalent degree directly related to the position the agency is seeking to fill.

(v) Positions must have progressively more responsible duties that provide career advancement opportunities (*i.e.,* positions must provide for career ladder advancement).

(c) *Extensions.* An agency may extend the Program period for up to an additional 120 days to cover rare or unusual circumstances or situations. The agency's Pathways MOU must identify criteria for approving extensions.

(d) *Qualifications.* An agency must evaluate candidates using OPM Qualification Standards for the occupation and grade level of the position being filled.

(e) *Promotions.* An agency may promote any Recent Graduate who meets the qualification requirements for the position. This provision does not confer entitlement to promotion.

(f) *Trial period.* The duration of the Recent Graduates appointment in the excepted service is a trial period.

§ 362.304 Movement between agencies.

(a) A Recent Graduate may apply for and accept a new Recent Graduates appointment with another agency covered by this part, as long as the agency meets all the requirements for participating in the Recent Graduates Program.

(b) To move to the new agency, the Recent Graduate must separate from the current employing agency.

(c) The new employing agency must appoint the Recent Graduate without a break in service.

(d) Time served under the previous agency's Recent Graduates Program is credited toward the Program requirements for noncompetitive conversion eligibility to the competitive service. Because there is no break in service, the Recent Graduate does not begin a new period in the Program upon moving to the new agency.

(e) The new employing agency's plan must identify requirements for Program completion and eligibility for noncompetitive conversion.

§ 362.305 Conversion to the competitive service.

(a) An agency may noncompetitively convert a Recent Graduate who is a U.S. citizen to a competitive service term or permanent position when the Recent Graduate has:

(1) Successfully completed at least 1-year of continuous service in addition to all the requirements of the Recent Graduates Program;

(2) Demonstrated successful job performance consistent with the applicable performance appraisal program established under the agency's approved performance appraisal system that results in a rating of record (or summary rating) of at least Fully Successful or equivalent and a recommendation for conversion by the first-level supervisor; and

(3) Met the OPM Qualification Standard for the competitive service position to which the Recent Graduate will be converted.

(b) An agency must make the noncompetitive conversion effective on the date the service requirement is met, or at the end of an agency-approved extension, if applicable.

§ 362.306 Reduction in force and termination.

(a) *Reduction in force.* Recent Graduates are in excepted service Tenure Group II for purposes of § 351.502 of this chapter. Expiration of the Recent Graduates appointment is not otherwise subject to part 351 of this chapter.

(b) *Terminations.* (1) Except as provided in paragraph (b)(2) of this section, as a condition of employment, a Recent Graduate appointment expires at the end of the agency prescribed Program period, plus any agency-approved extension, unless the Participant is selected for noncompetitive conversion under § 362.306.

(2) A Recent Graduate who held a career-conditional or career appointment in an agency immediately before entering the Program, and fails to complete the Program for reasons that are not related to misconduct, poor performance, or suitability, may, at the agency's discretion, be placed in a permanent competitive service position, as appropriate, in the employing agency.

Subpart D—Presidential Management Fellows Program

§ 362.401 Definitions.

For purposes of this subpart:

Agency PMF Coordinator is an individual, at the appropriate agency component level, who coordinates the placement, development, and other Program-related activities of PMFs appointed in his or her agency. The agency Pathways Programs Officer may also serve as the PMF Coordinator.

Executive Resources Board (ERB) has the same meaning as specified in § 317.501(a) of this section; in those agencies that are not required to have an ERB pursuant to that section, it means the senior agency official or officials

who have been given responsibility for executive resources management and oversight by the agency head.

Presidential Management Fellow (PMF) or *Fellow* is an individual appointed, at the GS–9, GS–11, or GS–12 level (or equivalent under a non-GS pay and classification system such as the Federal Wage System), in the excepted service under § 213.3402(c) of this chapter.

§ 362.402 Program administration.

(a) The Director may determine the number of Fellows who may be appointed during any given year. This determination will be based on input from the Chief Human Capital Officers Council, as well as input from agencies not represented on the Council.

(b) Thereafter, subject to the provisions and requirements of this chapter, an agency may appoint individuals selected by the Director as Fellows finalists according to its short-, medium-, and long-term senior leadership and related (senior policy, professional, technical, and equivalent) recruitment, development, and succession requirements.

(c) The Director will establish the qualification requirements for evaluating applicants for the PMF Program.

(d) An agency that hires Fellows in field locations outside the Washington, DC, Metropolitan Area may:

(1) In advance of making the appointment, discuss whether the finalist wants to do a developmental rotation to agency headquarters and, if so, make a commitment to allow and fund such a rotation, to the maximum extent practicable, in accordance with § 362.405(b) of this part; and

(2) Promote interaction among regional Fellows with the agency Federal Executive Board (FEB) and permit Fellows to attend FEB-sanctioned activities in that region.

§ 362.403 Announcement, eligibility, and selection.

(a) OPM will announce the opportunity to apply for the PMF Program and conduct a competition for the selection of finalists as set forth in this section.

(b) A Presidential Management Fellow is an individual who, within the previous 2 years, completed an advanced degree from a qualifying educational institution.

(c) An individual may apply for the PMF Program if:

(1) The individual has obtained an advanced degree within the 2-year period preceding the Program announcement described in paragraph (a) of this section, or

(2) The individual is still a student attending a qualifying educational institution, as defined in paragraph (2)(iii) of the definition of *Qualifying educational institution in* § 362.102, and he or she expects to complete a qualifying advanced degree by August 31 of the academic year in which the competition is held.

(d) An individual may apply for the PMF Program more than once as long as he or she meets the eligibility criteria. However, if an individual becomes a finalist and subsequently applies for the Program during the next open announcement, the individual will forfeit his or her status as a finalist.

(e) OPM will select Fellow finalists based on an OPM evaluation of each candidate's experience and accomplishments according to his or her application and the results of a rigorous structured assessment process.

(f) OPM will publish and provide participating agencies the Fellow finalists list for appointment consideration.

§ 362.404 Appointment and extension.

(a) *Appointments.* (1) An agency may make 2-year appointments to the PMF Program, pursuant to a Pathways MOU executed with the OPM, under Schedule D of the excepted service in accordance with part 302 of this chapter.

(2) An agency must appoint a PMF using the excepted service appointing authority provided by § 213.3402(c) of this chapter.

(3) OPM will establish an eligibility period during which agencies may appoint Fellow finalists.

(b) *Extension.* An agency may extend a Fellow's appointment for up to 120 days to cover rare or unusual circumstances or situations. The agency's Pathways MOU must identify the criteria for approving extensions.

(c) *Grade.* An agency may appoint a Fellow at the GS–09, GS–11, or GS–12 level or equivalent depending on his or her qualifications.

(d) *Trial period.* The duration of the PMF appointment in the excepted service is a trial period.

§ 362.405 Development, evaluation, promotion, and certification.

(a) *Individual Development Plans.* An agency must approve, within 45 days, an Individual Development Plan (IDP) for each of its Fellows that sets forth the specific developmental activities that are mutually agreed upon by each Fellow and his or her supervisor. The IDP must be developed in consultation with the Agency PMF Coordinator and/or the mentor assigned to the Fellow under paragraph (b)(3) of this section.

(b) *Required developmental activities.* (1) OPM will provide an orientation program for each class or cohort of Fellows and will provide information on available training opportunities known to it.

(2) The agency must provide each Fellow a minimum of 80 hours of formal interactive training per year that addresses the competencies outlined in the IDP. Mandatory annual training, such as information security and ethics training, does not count towards the 80-hour requirement.

(3) Within the first 90 days of a Fellow's appointment, the agency must assign the Fellow a mentor, who is a managerial employee outside the Fellow's chain of command.

(4) The agency must provide each Fellow with at least one rotational or developmental assignment with full-time management and/or technical responsibilities consistent with the Fellow's IDP. With respect to this requirement:

(i) Each Fellow must receive at least one developmental assignment of 4 to 6 months in duration, with management and/or technical responsibilities consistent with the Fellow's IDP. As an alternative, a Fellow may choose to participate in an agency-wide initiative or other Presidential or Administration initiative that will provide the Fellow with the experience he or she would have gained through the 4-to-6-month developmental assignment; and

(ii) The developmental assignment may be within the Fellow's organization, in another component of the agency, or in another Federal agency.

(5) The Fellow may receive other short-term rotational assignments of 1 to 6 months in duration, at the agency's discretion.

(6) Upon the request of OPM, the appointing agency must make Fellows available to assist in the assessment process for subsequent PMF classes. Any interactive training provided to a Fellow in connection with assisting OPM in the assessment process may be counted toward the minimum 80-hour training requirement in paragraph (b)(2) of this section.

(c) *Promotion.* An agency may promote any Fellow who meets the qualification requirements for the position. This provision does not confer entitlement to promotion.

(d) *Certification of completion.* (1) Upon completion of the Program, the agency's ERB must evaluate each Fellow and determine whether it can certify in writing that the Fellow met all of the requirements of the Program, including the performance and developmental

expectations set forth in the individual's performance plan and IDP. The ERB may consult the Fellow's mentor in reaching its determination.

(2) The ERB must notify the Fellow of its decision regarding certification of successful completion.

(3) ERB certifications must be forwarded to OPM.

(4)(i) If the ERB decides not to certify a Fellow, the Fellow may request reconsideration of that determination by the Director. Such reconsideration must be requested in writing, with appropriate documentation and justification, within 15 calendar days of the date of the agency's decision. The Director's decision on reconsideration is not subject to appeal.

(ii) The Fellow may continue in the Program pending the outcome of his or her request for reconsideration. The agency must continue to provide appropriate developmental activities during this period.

§ 362.406 Movement between agencies.

(a) At any time during his or her appointment in the Program, a Fellow may move to another agency covered by this part, as long as the agency meets all the requirements for participating in the PMF Program. To move from one agency to another during the Program, the Fellow must separate from the current agency. The new employing agency must appoint the Participant without a break in service.

(b) The Fellow does not begin a new Program period upon appointment by the new employing agency. Because there is no break in service, time served under the previous Program appointment will apply towards the completion of the Program with the new employing agency.

(c) An agency must notify OPM when appointing a Fellow currently appointed in another agency.

(d) If the move occurs within the first 6 months of the Fellow's appointment, the original appointing agency may request reimbursement of one-quarter of the placement fee from the new appointing agency.

§ 362.407 Withdrawal and readmission.

(a) *Withdrawal.* (1) A Fellow may withdraw from the Program at any time. Such withdrawal will be treated as a resignation from the Federal service; however, any obligations established upon admission and appointment (for example, as a result of accepting a recruitment incentive under part 575 of this chapter) still apply.

(2) A Fellow who held a permanent appointment in the competitive service in an agency immediately before entering the Program, and who withdraws from the Program for reasons that are not related to misconduct, poor performance, or suitability, may, at the employing agency's discretion, be placed in a permanent competitive service position, as appropriate, in that agency. The employing agency's determination in this regard is not subject to appeal.

(3) An agency must notify OPM when a Fellow withdraws from the Program.

(b) *Readmission.* (1) If a Fellow withdraws from the Program for reasons that are related to misconduct, poor performance, or suitability, as determined by the agency, he or she will not be readmitted to the Program at any time.

(2) If a Fellow withdraws from the Program for reasons that are not related to misconduct, poor performance, or suitability, he or she may petition the employing original agency for readmission and reappointment to the Program. Such a petition must be in writing and include appropriate justification. The agency may approve or deny the request for readmission. An agency must submit written notification of approved readmission requests to OPM. The individual's status in the Program upon readmission and reappointment must be addressed as part of the agency's submission. The Director may overrule the agency's decision to readmit and reappoint, and the Director's decision is not subject to appeal.

§ 362.408 Termination and reduction in force.

(a) *Termination.* (1) An agency may terminate a Fellow for reasons related to misconduct, poor performance, or suitability.

(2) As a condition of employment, a Fellow's appointment expires at the end of the 2-year Program period, plus any agency-approved extension, unless the Participant is selected for noncompetitive conversion. If an agency does not convert a Fellow at the end of the Program, as provided in § 362.409 of this part, or extend the individual's initial appointment under § 362.404, the appointment expires when certification for Program completion is denied or when the Director denies the agency's request for an extension.

(3) The agency must provide written notification to OPM when a Fellow is terminated for any reason.

(b) *Reduction in force.* Fellows are in the excepted service Tenure Group II for purposes of § 351.502 of this chapter.

§ 362.409 Conversion to the competitive service.

(a) A Fellow must complete the Program within the time limits prescribed in § 362.404 of this part, including any agency-approved extension. At the conclusion of that period, the Fellow may be converted, as provided in paragraph (b) of this section.

(b) An agency may convert, without a break in service, an ERB-certified Fellow to a competitive service term or permanent appointment.

PART 531—PAY UNDER THE GENERAL SCHEDULE

■ 20. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Public Law 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5305, 5333, 5334(a) and (b), and 7701(b)(2); Subpart D also issued under 5 U.S.C. 5335 and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304 and 5305; E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682; and E.O. 13106, 63 FR 68151, 3 CFR, 1998 Comp., p. 224.

Subpart B—Determining Rate of Basic Pay

■ 21. In § 531.212, revise paragraph (a)(3)(v) to read as follows:

§ 531.212 Superior qualifications and special needs pay-setting authority.

(a) * * *

(3) * * *

(v) Employment under an Internship Program appointment under § 213.3402(a) of this chapter.

* * * * *

PART 536—GRADE AND PAY RETENTION

■ 22. The authority citation for part 536 continues to read as follows:

Authority: 5 U.S.C. 5361–5366; sec. 4 of the Performance Management and Recognition System Termination Act of 1993 (Pub. L. 103–89), 107 Stat. 981; § 536.301(b) also issued under 5 U.S.C. 5334(b); § 536.308 also issued under section 301(d)(2) of the Federal Workforce Flexibility Act of 2004 (Pub. L. 108–411), 118 Stat. 2305; § 536.405 also issued under 5 U.S.C. 552, Freedom of Information Act, Public Law 92–502.

Subpart A—General Provisions

■ 23. In § 536.103, revise the definition of *management action* to read as follows:

§ 536.103 Definitions.

* * * * *

Management action means an action (not for personal cause) by an agency official not initiated or requested by an employee which may adversely affect the employee's grade or rate of basic pay. However, an employee's placement in or transfer to a position under a formal employee development program established by an agency for recruitment and employee advancement purposes (*e.g.,* Recent Graduates Program) is considered a management action even though the employee initiates or requests such placement or transfer.

* * * * *

Subpart C—Pay Retention

■ 24. In § 536.301, revise paragraph (a)(5) to read as follows:

§ 536.301 Mandatory pay retention.

(a) * * *

(5) A management action that places an employee in a formal employee development program generally utilized Governmentwide (*e.g.,* Recent Graduates Program); or

* * * * *

PART 537—REPAYMENT OF STUDENT LOANS

■ 25. The authority citation for part 537 continues to read as follows:

Authority: 5 U.S.C. 5379(g).

■ 26. In § 537.102, revise paragraphs (6) and (7) in the definition of *time-limited appointment* to read as follows:

§ 537.102 Definitions.

* * * * *

Time-limited appointment * * *

(6) A Presidential Management Fellows Program appointment under § 213.3402(c) of this chapter;

(7) A Recent Graduates Program appointment under § 213.3402(b) of this chapter; and

* * * * *

PART 550—PAY ADMINISTRATION (GENERAL)

Subpart B—Advances in Pay

■ 27. Revise the authority citation for subpart B of part 550 to read as follows:

Authority: 5 U.S.C. 5524a, 5545a(h)(2)(B); E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316.

■ 28. In § 550.202, revise paragraph (c) of the definition of *newly appointed* to read as follows:

§ 550.202 Definitions.

* * * * *

Newly appointed * * *

(c) A permanent appointment in the competitive service following termination of employment in an Internship Program (as described in 5 CFR part 362, subpart B), provided such employee—

* * * * *

Subpart G—Severance Pay

■ 29. The authority citation for subpart G of part 550 continues to read as follows:

Authority: 5 U.S.C. 5595; E.O. 11257, 3 CFR, 1964–1965 Comp., p. 357.

■ 30. In § 550.703, revise paragraph (f)(5) in the definition of *nonqualifying appointment* to read as follows:

§ 550.703 Definitions.

* * * * *

Nonqualifying appointment * * *.

(f) * * *

(5) A Presidential Management Fellows Program appointment under § 213.3402(c) of this chapter.

* * * * *

Subpart M—Firefighter Pay

■ 31. The authority citation for subpart M of part 550 continues to read as follows:

Authority: 5 U.S.C. 5545b, 5548, and 5553.

■ 32. In § 550.1302, revise paragraph (2)(iii) of the definition of *firefighter* to read as follows:

§ 550.1302 Definitions.

* * * * *

Firefighter * * *.

(2) * * *

(iii) Covered by the General Schedule and classified in the GS–0099, General Student Trainee Series (as required by § 362.203(e) of this chapter), if the position otherwise would be classified in the GS–0081 series.

* * * * *

PART 575—RECRUITMENT, RELOCATION, AND RETENTION INCENTIVES; SUPERVISORY DIFFERENTIALS; AND EXTENDED ASSIGNMENT INCENTIVES

■ 33. The authority citation for part 575 continues to read as follows:

Authority: 5 U.S.C. 1104(a)(2) and 5307; subparts A and B also issued under 5 U.S.C. 5753 and sec. 101, Pub. L. 108–411, 118 Stat. 2305; subpart C also issued under 5 U.S.C. 5754 and sec. 101, Pub. L. 108–411, 118 Stat. 2305; subpart D also issued under 5 U.S.C. 5755; subpart E also issued under 5 U.S.C. 5757 and sec. 207 of Pub. L. 107–273, 116 Stat. 1780.

Subpart A—Recruitment Incentives

■ 34. In § 575.102, revise paragraph (3)(vi) in the definition of *newly appointed* to read as follows:

§ 575.102 Definitions.

* * * * *

Newly appointed * * *.

(3) * * *

(vi) Employment under an Internship Program appointment under § 213.3402(a) of this chapter.

* * * * *

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 35. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.301 also issued under sec. 311 of Pub. L. 111–3, 123 Stat. 64; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521; Sec. 890.112 also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604; Sec. 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; Sec. 890.102 also issued under sections 11202(f), 11232(e), 11246(b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section 721 of Pub. L. 105–261, 112 Stat. 2061.

■ 36. In § 890.102, revise paragraph (c)(2) to read as follows:

§ 890.102 Coverage.

* * * * *

(c) * * *

(2) An employee who is expected to work less than 6 months in each year, except for an employee who receives an appointment of at least 1 year's duration as an Intern under § 213.3402(a) of this chapter and who is expected to be in a pay status for at least one-third of the total period of time from the date of the first appointment to the completion of the Internship Program.

* * * * *

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Part IV

United States Sentencing Commission

Sentencing Guidelines for United States Courts; Notice

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of submission to Congress of amendments to the sentencing guidelines effective November 1, 2012.

SUMMARY: Pursuant to its authority under 28 U.S.C. § 994(p), the Commission has promulgated amendments to the sentencing guidelines, policy statements, commentary, and statutory index. This notice sets forth the amendments and the reason for each amendment.

DATES: The Commission has specified an effective date of November 1, 2012, for the amendments set forth in this notice.

FOR FURTHER INFORMATION CONTACT: Jeanne Doherty, Office of Legislative and Public Affairs, 202–502–4502. The amendments set forth in this notice also may be accessed through the Commission's Web site at *www.ussc.gov.*

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for federal sentencing courts pursuant to 28 U.S.C. § 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. § 994(o) and generally submits guideline amendments to Congress pursuant to 28 U.S.C. § 994(p) not later than the first day of May each year. Absent action of Congress to the contrary, submitted amendments become effective by operation of law on the date specified by the Commission (generally November 1 of the year in which the amendments are submitted to Congress).

Notice of proposed amendments was published in the **Federal Register** on January 19, 2012 (*see* 77 FR 2778). The Commission held a public hearing on the proposed amendments in Washington, DC, on March 14, 2012. On April 30, 2012, the Commission submitted these amendments to Congress and specified an effective date of November 1, 2012.

Authority: 28 U.S.C. § 994(a), (o), and (p); USSC Rules of Practice and Procedure 4.1.

Patti B. Saris,

Chair.

1. *Amendment:* The Commentary to § 2B1.1 captioned ''Application Notes'' is amended in Note 3(E) by adding at the end the following:

''(iii) Notwithstanding clause (ii), in the case of a fraud involving a mortgage loan, if the collateral has not been disposed of by the time of sentencing, use the fair market value of the collateral as of the date on which the guilt of the defendant has been established, whether by guilty plea, trial, or plea of *nolo contendere.*

In such a case, there shall be a rebuttable presumption that the most recent tax assessment value of the collateral is a reasonable estimate of the fair market value. In determining whether the most recent tax assessment value is a reasonable estimate of the fair market value, the court may consider, among other factors, the recency of the tax assessment and the extent to which the jurisdiction's tax assessment practices reflect factors not relevant to fair market value.'';

in Note 3(F) by adding at the end the following:

''(ix) *Fraudulent Inflation or Deflation in Value of Securities or Commodities.*—In a case involving the fraudulent inflation or deflation in the value of a publicly traded security or commodity, there shall be a rebuttable presumption that the actual loss attributable to the change in value of the security or commodity is the amount determined by—

(I) calculating the difference between the average price of the security or commodity during the period that the fraud occurred and the average price of the security or commodity during the 90-day period after the fraud was disclosed to the market, and

(II) multiplying the difference in average price by the number of shares outstanding.

In determining whether the amount so determined is a reasonable estimate of the actual loss attributable to the change in value of the security or commodity, the court may consider, among other factors, the extent to which the amount so determined includes significant changes in value not resulting from the offense (*e.g.,* changes caused by external market forces, such as changed economic circumstances, changed investor expectations, and new industry-specific or firm-specific facts, conditions, or events).'';

in Note 12(A) by adding at the end the following:

''(v) One or more of the criteria in clauses (i) through (iv) was likely to result from the offense but did not result from the offense because of federal government intervention, such as a 'bailout'.'';

in Note 12(B)(ii) by adding at the end the following:

''(VII) One or more of the criteria in subclauses (I) through (VI) was likely to result from the offense but did not result from the offense because of federal government intervention, such as a 'bailout'.'';

in Note 19(A)(iv) by inserting before the period at the end the following: '', such as a risk of a significant disruption of a national financial market'';

and in Note 19(C) by adding after the first paragraph the following new paragraph:

''For example, a securities fraud involving a fraudulent statement made publicly to the market may produce an aggregate loss amount that is substantial but diffuse, with relatively small loss amounts suffered by a relatively large number of victims. In such a case, the loss table in subsection (b)(1) and the victims table in subsection (b)(2) may combine to produce an offense level that substantially overstates the seriousness of the offense. If so, a downward departure may be warranted.''.

Section 2B1.4(b) is amended by striking ''Characteristic'' and inserting ''Characteristics''; and by adding at the end the following:

''(2) If the offense involved an organized scheme to engage in insider trading and the offense level determined above is less than level 14, increase to level 14.''.

The Commentary to § 2B1.4 captioned ''Application Note'' is amended in the caption by striking ''Note'' and inserting ''Notes''; by redesignating Note 1 as Note 2 and inserting before Note 2 (as so redesignated) the following:

''1. *Application of Subsection (b)(2).*—For purposes of subsection (b)(2), an 'organized scheme to engage in insider trading' means a scheme to engage in insider trading that involves considered, calculated, systematic, or repeated efforts to obtain and trade on inside information, as distinguished from fortuitous or opportunistic instances of insider trading.

The following is a non-exhaustive list of factors that the court may consider in determining whether the offense involved an organized scheme to engage in insider trading:

(A) The number of transactions;

(B) The dollar value of the transactions;

(C) The number of securities involved;

(D) The duration of the offense;

(E) The number of participants in the scheme (although such a scheme may exist even in the absence of more than one participant);

(F) The efforts undertaken to obtain material, nonpublic information;

(G) The number of instances in which material, nonpublic information was obtained; and

(H) The efforts undertaken to conceal the offense.'';

in Note 2 (as so redesignated) by striking ''only''; and by adding at the end the following new paragraph:

''Furthermore, § 3B1.3 should be applied if the defendant's employment in a position that involved regular participation or

professional assistance in creating, issuing, buying, selling, or trading securities or commodities was used to facilitate significantly the commission or concealment of the offense. It would apply, for example, to a hedge fund professional who regularly participates in securities transactions or to a lawyer who regularly provides professional assistance in securities transactions, if the defendant's employment in such a position was used to facilitate significantly the commission or concealment of the offense. It ordinarily would not apply to a position such as a clerical worker in an investment firm, because such a position ordinarily does not involve special skill. *See* § 3B1.3, comment. (n. 4).''.

The Commentary to § 2B1.4 captioned ''Background'' is amended by adding at the end the following new paragraph:

''Subsection (b)(2) implements the directive to the Commission in section 1079A(a)(1)(A) of Public Law 111B203.''.

Reason for Amendment: This amendment responds to the two directives to the Commission in the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111-203 (the ''Act''). The first directive relates to securities fraud and similar offenses, and the second directive relates to mortgage fraud and financial institution fraud.

Securities Fraud and Similar Offenses

Section 1079A(a)(1)(A) of the Act directs the Commission to ''review and, if appropriate, amend'' the guidelines and policy statements applicable to ''persons convicted of offenses relating to securities fraud or any other similar provision of law, in order to reflect the intent of Congress that penalties for the offenses under the guidelines and policy statements appropriately account for the potential and actual harm to the public and the financial markets from the offenses.'' Section 1079A(a)(1)(B) provides that in promulgating any such amendment the Commission shall—

(i) Ensure that the guidelines and policy statements, particularly section 2B1.1(b)(14) and section 2B1.1(b)(17) (and any successors thereto), reflect—

(I) The serious nature of the offenses described in subparagraph (A);

(II) The need for an effective deterrent and appropriate punishment to prevent the offenses; and

(III) The effectiveness of incarceration in furthering the objectives described in subclauses (I) and (II);

(ii) Consider the extent to which the guidelines appropriately account for the potential and actual harm to the public and the financial markets resulting from the offenses;

(iii) Ensure reasonable consistency with other relevant directives and guidelines and Federal statutes;

(iv) Make any necessary conforming changes to guidelines; and

(v) Ensure that the guidelines adequately meet the purposes of sentencing, as set forth in section 3553(a)(2) of title 18, United States Code.

The amendment responds to this directive in two ways. First, the amendment amends the fraud guideline, § 2B1.1 (Theft, Property Destruction, and Fraud), to provide a special rule for determining actual loss in cases involving the fraudulent inflation or deflation in the value of a publicly traded security or commodity. Case law and comments received by the Commission indicate that determinations of loss in cases involving securities fraud and similar offenses are complex and that a variety of different methods are in use, possibly resulting in unwarranted sentencing disparities.

The amendment amends § 2B1.1 to provide a special rule regarding how to calculate actual loss in these types of cases. Specifically, the amendment creates a new Application Note 3(F)(ix) which establishes a rebuttable presumption that ''the actual loss attributable to the change in value of the security or commodity is the amount determined by (I) calculating the difference between the average price of the security or commodity during the period that the fraud occurred and the average price of the security or commodity during the 90-day period after the fraud was disclosed to the market, and (II) multiplying the difference in average price by the number of shares outstanding.'' The special rule further provides that, ''[i]n determining whether the amount so determined is a reasonable estimate of the actual loss attributable to the change in value of the security or commodity, the court may consider, among other factors, the extent to which the amount so determined includes significant changes in value not resulting from the offense (*e.g.,* changes caused by external market forces, such as changed economic circumstances, changed investor expectations, and new industry-specific or firm-specific facts, conditions, or events).''

The special rule is based upon what is sometimes referred to as the ''modified rescissory method'' and should ordinarily provide a ''reasonable estimate of the loss'' as required by Application Note 3(C). This special rule is intended to provide courts a workable and consistent formula for calculating loss that ''resulted from the offense.'' *See* § 2B1.1, comment. (n.3(A)(i)). By averaging the stock price during the period in which the fraud occurred and a set 90-day period after the fraud was discovered, the special rule reduces the impact on the loss calculation of factors other than the fraud, such as overall growth or decline in the price of the stock. *See, e.g., United States* v. *Bakhit,* 218 F. Supp. 2d 1232 (C.D. Cal. 2002); *United States* v. *Snyder,* 291 F.3d 1291 (11th Cir. 2002); *United States* v. *Brown,* 595 F.3d 498 (3d Cir. 2010); *see also* 15 U.S.C. 78u-4(e) (statutorily setting forth a similar method for loss calculation in the context of private securities litigation). Furthermore, applying this special rule could ''eliminate[], or at least reduce[], the complexity, uncertainty, and expense inherent in attempting to determine out-of-pocket losses on a case-by-case basis.'' *See United States* v. *Grabske,* 260 F. Supp. 2d. 866, 873–74 (N.D. Cal. 2002).

By applying a rebuttable presumption, however, the amendment also provides sufficient flexibility for a court to consider the extent to which the amount determined under the special rule includes significant changes in value not resulting from the offense (*e.g.,* changes caused by external market forces, such as changed economic circumstances, changed investor expectations, and new industry-specific or firm-specific facts, conditions, or events).

The amendment also responds to the first directive by amending the insider trading guideline, § 2B1.4 (Insider Trading). First, it provides a new specific offense characteristic if the offense involved an ''organized scheme to engage in insider trading.'' In such a case, the new specific offense characteristic provides a minimum offense level of 14. The commentary is also amended to provide factors the court may consider in determining whether the new minimum offense level applies.

The amendment reflects the Commission's view that a defendant who engages in considered, calculated, systematic, or repeated efforts to obtain and trade on inside information (as opposed to fortuitous or opportunistic instances of insider trading) warrants, at minimum, a short but definite period of incarceration. Sentencing data indicate that when a defendant engages in an organized insider trading scheme, the gain from the offense ordinarily triggers an enhancement under § 2B1.4(b)(1) of sufficient magnitude to result in a guideline range that requires a period of imprisonment. The amendment, however, ensures that the guidelines require a period of incarceration even in such a case involving relatively little gain.

The amendment also amends the commentary to § 2B1.4 to provide more guidance on the applicability of § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) in insider trading cases. In particular, the new commentary in Application Note 2 provides that § 3B1.3 should be applied if the defendant's employment in a position that involved regular participation or professional assistance in creating, issuing, buying, selling, or trading securities or commodities was used to facilitate significantly the commission or concealment of the offense. The commentary further provides examples of positions that may qualify for the adjustment, including a hedge fund professional who regularly participates in securities transactions or a lawyer who regularly provides professional assistance in securities transactions. Individuals who occupy such positions possess special knowledge regarding the financial markets and the rules prohibiting insider trading, and generally are viewed as more culpable. *See* § 3B1.3, comment. (backg'd). The commentary also provides as an example of a position that would not qualify for the adjustment in § 3B1.4 a clerical worker in an investment firm. Such a position ordinarily does not involve special skill and is not generally viewed as more culpable.

Mortgage Fraud and Financial Institution Fraud

Section 1079A(a)(2)(A) of the Act directs the Commission to ''review and, if appropriate, amend'' the guidelines and policy statements applicable to ''persons convicted of fraud offenses relating to financial institutions or federally related mortgage loans and any other similar provisions of law, to reflect the intent of Congress that the penalties for the offenses under the guidelines and policy statements ensure appropriate terms of imprisonment for offenders involved in substantial bank frauds or other frauds relating to financial institutions.'' Section 1079A(a)(2)(B) of the Act provides that, in promulgating any such amendment, the Commission shall—

(i) Ensure that the guidelines and policy statements reflect—

(I) The serious nature of the offenses described in subparagraph (A);

(II) The need for an effective deterrent and appropriate punishment to prevent the offenses; and

(III) The effectiveness of incarceration in furthering the objectives described in subclauses (I) and (II);

(ii) Consider the extent to which the guidelines appropriately account for the potential and actual harm to the public and the financial markets resulting from the offenses;

(iii) Ensure reasonable consistency with other relevant directives and guidelines and Federal statutes;

(iv) Make any necessary conforming changes to guidelines; and

(v) Ensure that the guidelines adequately meet the purposes of sentencing, as set forth in section 3553(a)(2) of title 18, United States Code.

The amendment responds to this directive in two ways.

First, the amendment adds language to the credits against loss rule, found in Application Note 3(E) of the commentary to § 2B1.1. Application Note 3(E)(i) generally provides that the determination of loss under subsection (b)(1) shall be reduced by the money returned and the fair market value of the property returned and services rendered to the victim before the offense was detected. In the context of a case involving collateral pledged or otherwise provided by the defendant, Application Note 3(E)(ii) provides that the loss to the victim shall be reduced by either ''the amount the victim has recovered at the time of sentencing from disposition of the collateral, or if the collateral has not been disposed of by that time, the fair market value of the collateral at the time of sentencing.''

The Commission received comment that, in cases involving mortgage fraud where the collateral has not been disposed of by the time of sentencing, the fair market value of the collateral may be difficult to determine and may require frequent updating, especially in cases involving multiple properties. The comments further indicate that the lack of a uniform process may result in unwarranted sentencing disparities.

The amendment responds to these concerns by establishing a new Application Note 3(E)(iii) applicable to fraud cases involving a mortgage loan where the underlying collateral has not been disposed of by the time of sentencing. In such a case, new Application Note 3(E)(iii) makes two changes to the calculation of credits against loss. First, the note changes the date on which the fair market value of the collateral is determined, from the time of sentencing to the date on which the guilt of the defendant has been established. This change is intended to avoid the need to reassess the fair market value of such collateral on multiple occasions up to the date of sentencing. Second, it establishes a rebuttable presumption that the most recent tax assessment value of the collateral is a reasonable estimate of the fair market value. In determining whether the tax assessment is a reasonable estimate of fair market value, the note further provides that the court may consider the recency of the tax assessment and the extent to which the jurisdiction's tax assessment practices reflect factors not relevant to fair market value, among other factors.

By structuring the special rule in this manner, the amendment addresses the need to provide a uniform practicable method for determining fair market value of undisposed collateral while providing sufficient flexibility for courts to address differences among jurisdictions regarding how closely the most recent tax assessment correlates to fair market value. The Commission heard concerns, for example, that, in some jurisdictions, the most recent tax assessment may be outdated or based upon factors, such as the age or status of the homeowner, that have no correlation to fair market value.

The amendment also responds to the second directive by amending the commentary regarding the application of § 2B1.1(b)(15)(B), which provides an enhancement of 4 levels if the offense involved specific types of financial harms (*e.g.,* jeopardizing a financial institution or organization). This commentary, contained in Application Note 12 to § 2B1.1, provides a non-exhaustive list of factors the court shall consider in determining whether, as a result of the offense, the safety and soundness of a financial institution or an organization that was a publicly traded company or that had more than 1,000 employees was substantially jeopardized. For example, in the context of financial institutions, the court shall consider whether the financial institution became insolvent, was forced to reduce benefits to pensioners or insureds, was unable on demand to refund fully any deposit, payment, or investment, or was so depleted of its assets as to be forced to merge with another institution. Similarly, in the context of a covered organization, the court shall consider whether the organization became insolvent or suffered a substantial reduction in the value of its assets, filed for bankruptcy, suffered a substantial reduction in the value of its equity securities or its employee retirement accounts, or substantially reduced its workforce or employee pension benefits.

The amendment amends Application Note 12 to add as a new consideration whether one of the listed harms was likely to result from the offense, but did not result from the offense because of federal government intervention, such as a ''bailout.'' This amendment reflects the Commission's intent that

§ 2B1.1(b)(15)(B) account for the risk of harm from the defendant's conduct and its view that a defendant should not avoid the application of the enhancement because the harm that was otherwise likely to result from the offense conduct did not occur because of fortuitous federal government intervention.

Departure Provisions

Finally, the amendment also responds to the Act's directives by amending the departure provisions in § 2B1.1 to provide two examples of cases in which a departure may be warranted.

First, the amendment amends Application Note 19(A)(iv), which provides that an upward departure may be warranted if the offense created a risk of substantial loss beyond the loss determined for purposes of subsection (b)(1). The amendment adds ''risk of a significant disruption of a national financial market'' as an example of such a risk. This part of the amendment responds to the requirement in the Act to consider whether the guidelines applicable to the offenses covered by the directives appropriately ''account for the potential and actual harm to the public and the financial markets[.]''

The amendment also amends Application Note 19(C), which provides that a downward departure may be warranted if the offense level substantially overstates the seriousness of the offense, by adding an example of a case in which such a departure may be appropriate. The example provides that ''a securities fraud involving a fraudulent statement made publicly to the market may produce an aggregate loss amount that is substantial but diffuse, with relatively small loss amounts suffered by a relatively large number of victims,'' and that, ''in such a case, the loss table in subsection (b)(1) and the victims table in subsection (b)(2) may combine to produce an offense level that substantially overstates the seriousness of the offense.'' This part of the amendment responds to concerns raised in comment and case law that the cumulative impact of the loss table and the victims table may overstate the seriousness of the offense in certain cases.

2. *Amendment:* The Commentary to § 2D1.1 captioned ''Application Notes'' is amended in Note 10(D) in the subdivision captioned ''Cocaine and Other Schedule I and II Stimulants (and their immediate precursors)'' by inserting after the entry relating to N-N-Dimethylamphetamine the following new entry:

''1 gm of N-Benzylpiperazine = 100 gm of marihuana''.

Reason for Amendment: This amendment responds to concerns raised by the Second Circuit Court of Appeals and others regarding the sentencing of offenders convicted of offenses involving BZP (N-Benzylpiperazine), which is a Schedule I stimulant. *See United States* v. *Figueroa,* 647 F.3d 466 (2d Cir. 2011). The amendment establishes a marijuana equivalency for BZP offenses in the Drug Equivalency Table provided in Application Note 10(D) in § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy). The marijuana equivalency established by the amendment provides that 1 gram of BZP equals 100 grams of marijuana.

Prior to the amendment, the Drug Equivalency Table did not include a marijuana equivalency for BZP. As a result, in offenses involving BZP, the court determined the base offense level using the marijuana equivalency of ''the most closely related controlled substance'' referenced in § 2D1.1. *See* § 2D1.1, comment. (n. 5). In determining the most closely related controlled substance, the commentary directs the court to consider (1) whether the controlled substance not referenced in § 2D1.1 has a chemical structure that is substantially similar to a controlled substance that is referenced in § 2D1.1, (2) whether the controlled substance not referenced in § 2D1.1 has a stimulant, depressant, or hallucinogenic effect similar to a controlled substance referenced in the guideline, and (3) whether a lesser or greater quantity of the controlled substance not referenced in § 2D1.1 is needed to produce a substantially similar effect as a controlled substance that is referenced in § 2D1.1.

In applying these factors, courts have reached different conclusions regarding which controlled substance referenced in § 2D1.1 is most closely related to BZP and have therefore used different marijuana equivalencies in sentencing BZP offenders. The Commission's review of case law and sentencing data indicate that some district courts have found that the controlled substance most closely related to BZP is amphetamine and used the marijuana equivalency for amphetamine, *see United States* v. *Major,* 801 F. Supp. 2d 511, 514 (E.D. Va. 2011) (using the marijuana equivalency for amphetamine at full potency), while other district courts have found that the controlled substance most related to BZP is MDMA, but at varying potencies. *See United States* v. *Bennett,* 659 F.3d 711, 715–16 (8th Cir. 2011) (affirming a district court's use of the marijuana equivalency for MDMA at full potency); *United States* v. *Rose,* 722 F. Supp. 2d 1286, 1289 (M.D. Ala. 2010) (concluding that BZP is most closely related to MDMA, but imposing a variance to reflect BZP's reduced potency compared to MDMA). The different findings of which controlled substance is the most closely related to BZP, and the application of different potencies of those controlled substances, have resulted in courts imposing vastly different sentence lengths for the same conduct.

The Commission reviewed scientific literature and received expert testimony and comment relating to BZP and concluded that BZP is a stimulant with pharmacologic properties similar to that of amphetamine, but is only one-tenth to one-twentieth as potent as amphetamine, depending on the particular user's history of drug abuse. Accordingly, in order to promote uniformity in sentencing BZP offenders and to reflect the best available scientific evidence, the amendment establishes a marijuana equivalency of 1 gram of BZP equals 100 grams of marijuana. This corresponds to one-twentieth of the marijuana equivalency for amphetamine, which is 1 gram of amphetamine equals 2 kilograms (or 2,000 grams) of marijuana.

3. *Amendment:* Section 2D1.11 is amended in subsection (b) by adding at the end the following:

''(6) If the defendant meets the criteria set forth in subdivisions (1)–(5) of subsection (a) of § 5C1.2 (Limitation on Applicability of Statutory Minimum Sentences in Certain Cases), decrease by 2 levels.''.

The Commentary to 2D1.11 captioned ''Application Notes'' is amended by adding at the end the following:

''9. *Applicability of Subsection (b)(6).*CThe applicability of subsection (b)(6) shall be determined without regard to the offense of conviction. If subsection (b)(6) applies, § 5C1.2(b) does not apply. *See* § 5C1.2(b)(2)(requiring a minimum offense level of level 17 if the 'statutorily required minimum sentence is at least five years').''.

Reason for Amendment: This amendment adds a new specific offense characteristic at subsection (b)(6) of § 2D1.11 (Unlawfully Distributing, Importing, Exporting or Possessing a Listed Chemical; Attempt or Conspiracy) that provides a 2-level decrease if the defendant meets the criteria set forth in subdivisions (1)–(5) of subsection (a) of § 5C1.2 (Limitation on Applicability of Statutory Minimum Sentences in Certain Cases) (commonly referred to as the ''safety valve'' criteria). The new specific offense characteristic

in § 2D1.11 parallels the existing 2-level decrease at subsection (b)(16) of § 2D1.1(Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy).

The Commission in 1995 created the 2-level reduction in § 2D1.1 for offenders who meet the safety valve criteria in response to a directive in section 80001 of the Violent Crime Control and Law Enforcement Act of 1994, Public Law 103–322. Section 80001 provided an exception to otherwise applicable statutory minimum sentences for defendants convicted of specified drug offenses and who meet the criteria specified in 18 U.S.C. 3553(f)(1)–(5), and directed the Commission to promulgate guidelines to carry out these purposes. The reduction in § 2D1.1 initially was limited to defendants whose offense level was level 26 or greater, *see* USSG App. C, Amendment 515 (effective November 1, 1995), but was subsequently expanded to apply to offenders with an offense level lower than level 26 to address proportionality concerns. *See* USSG App. C, Amendment 624 (effective November 1, 2001). Specifically, the Commission determined that limiting the applicability of the reduction to defendants with an offense level of level 26 or greater ''is inconsistent with the general principles underlying the two-level reduction * * * to provide lesser punishment for first time, nonviolent offenders.'' *Id.*

For similar reasons of proportionality, this amendment expands application of the 2-level reduction to offenses involving list I and list II chemicals sentenced under § 2D1.11. List I chemicals are important to the manufacture of a controlled substance and usually become part of the final product, while list II chemicals are generally used as solvents, catalysts, and reagents. *See* USSG § 2D1.11, comment. (backg'd.). Section 2D1.11 is generally structured to provide base offense levels that are tied to, but less severe than, the base offense levels in § 2D1.1 for offenses involving the final product. The Commission determined that adding the 2-level reduction for meeting the safety valve criteria in § 2D1.11 would promote the proportionality the Commission has intended to achieve between §§ 2D1.1 and 2D1.11.

The amendment also adds new commentary relating to the ''safety valve'' reduction in § 2D1.11 that is consistent with the commentary relating to the ''safety valve'' reduction in § 2D1.1. *See* USSG § 2D1.1, comment. (n. 21). The commentary makes clear that the new 2-level reduction in § 2D1.11 applies regardless of the offense of conviction, and that the minimum offense level of 17 in subsection (b) of § 5C1.2 (Limitation on Applicability of Statutory Minimum Sentences in Certain Cases) does not apply. Section § 5C1.2(b) provides for an offense level not less than level 17 for defendants who meet the criteria of subdivisions (1)–(5) of section (a) in § 5C1.2 and for whom the statutorily required minimum sentence is at least 5 years. *See* USSG App. C, Amendment 624 (effective November 1, 2001). Since none of the offenses referenced to § 2D1.11 carries a statutory mandatory minimum, the minimum offense level of 17 at § 5C1.2(b) does not affect application of the new 2-level reduction in § 2D1.11.

4. *Amendment:* The Commentary to § 2L1.2 captioned ''Application Notes'' is amended in Note 1(B)(vii) by inserting before the period at the end the following: '', but only if the revocation occurred before the defendant was deported or unlawfully remained in the United States''.

Reason for Amendment: This amendment responds to a circuit conflict over the application of the enhancements found at § 2L1.2(b)(1)(A) and (B) to a defendant who was sentenced on two or more occasions for the same drug trafficking conviction (*e.g.,* because of a revocation of probation, parole, or supervised release), such that there was a sentence imposed before the defendant's deportation, then an additional sentence imposed after the deportation. The amendment resolves the conflict by amending the definition of ''sentence imposed'' in Application Note 1(B)(vii) to § 2L1.2 (Unlawfully Entering or Remaining in the United States) to state that the length of the sentence imposed includes terms of imprisonment given upon revocation of probation, parole, or supervised release, but ''only if the revocation occurred before the defendant was deported or unlawfully remained in the United States.''

Section 2L1.2(b)(1) generally reflects the Commission's determination that both the seriousness and the timing of the prior offense for which the defendant was deported are relevant to assessing the defendant's culpability for the illegal reentry offense. A defendant who was deported after a conviction for a felony drug trafficking offense receives an enhancement under either prong (A) or (B) of subsection (b)(1), depending on the length of the sentence imposed. If the sentence imposed was more than 13 months, the defendant receives a 16-level enhancement to the base offense level under prong (A). If the sentence imposed was 13 months or less, the defendant receives a 12-level enhancement under prong (B). However, for defendants whose prior convictions are remote in time and thus do not receive criminal history points, these enhancements are reduced to 12 levels and 8 levels, respectively.

The majority of circuits that have considered the meaning of ''sentence imposed'' in this context have held that the later, additional sentence imposed after deportation does not lengthen the sentence imposed for purposes of the subsection (b)(1) enhancement. *See United States* v. *Bustillos-Pena,* 612 F.3d 863 (5th Cir. 2010); *United States* v. *Lopez,* 634 F.3d 948 (7th Cir. 2011); *United States* v. *Rosales-Garcia,* 667 F.3d 1348 (10th Cir. 2012); *United States* v. *Guzman-Bera,* 216 F.3d 1019 (11th Cir. 2000). Under the majority approach, if the sentence imposed was 13 months or less before the defendant was deported, and was only increased to more than 13 months after the deportation, the defendant is not subject to the enhancement in prong (A) because the ''sentence imposed'' includes only the sentence imposed before the deportation. Under this approach, such a defendant receives the enhancement in prong (B) instead.

The Second Circuit has reached the contrary conclusion, holding that defendants who had their sentences increased to more than 13 months upon revocation after deportation are subject to the enhancement in prong (A) because the ''sentence imposed'' includes the additional revocation sentence imposed after deportation. *See United States* v. *Compres-Paulino,* 393 F.3d 116 (2d Cir. 2004).

The amendment adopts the approach taken by the majority of circuits, with the result that the term of imprisonment imposed upon revocation counts toward the calculation of the offense level in § 2L1.2 only if it was imposed before the defendant was deported or unlawfully remained in the United States. According to public comment and testimony received by the Commission, and as courts have observed, the circumstances under which persons are found present in this country and have their probation, parole, or supervised release revoked for a prior offense vary widely. *See Bustillos-Pena,* 612 F.3d at 867–68 (describing differences among revocation proceedings). In some jurisdictions, the revocation is typically based on the offender's illegal return, while in others, the revocation is typically based on the offender's committing an additional crime.

Furthermore, in some cases revocation proceedings commonly occur before the offender is sentenced on the illegal reentry offense, while in other cases the revocation occurs after the federal sentencing. *See Rosales-Garcia,* 667 F.3d at 1354 (observing that considering post-deportation revocation sentences could result in disparities based on the ''happenstance'' of whether that revocation occurred before or after the prosecution for the illegal reentry offense). Therefore, assessing the seriousness of the prior crime based on the sentence imposed before deportation should result in more consistent application of the enhancements in § 2L1.2(b)(1)(A) and (B) and promote uniformity in sentencing.

5. *Amendment:* Section 2L2.2 is amended in subsection (b) by adding at the end the following:

''(4) (Apply the Greater):

(A) If the defendant committed any part of the instant offense to conceal the defendant's membership in, or authority over, a military, paramilitary, or police organization that was involved in a serious human rights offense during the period in which the defendant was such a member or had such authority, increase by 2 levels. If the resulting offense level is less than level 13, increase to level 13.

(B) If the defendant committed any part of the instant offense to conceal the defendant's participation in (i) the offense of incitement to genocide, increase by 6 levels; or (ii) any other serious human rights offense, increase by 10 levels. If clause (ii) applies and the resulting offense level is less than level 25, increase to level 25.''.

The Commentary to 2L2.2 captioned ''Application Notes'' is amended by redesignating Notes 4 and 5 as Notes 5 and 6, respectively; and by inserting after Note 3 the following:

''4. *Application of Subsection (b)(4)*—For purposes of subsection (b)(4):

'Serious human rights offense' means (A) violations of federal criminal laws relating to genocide, torture, war crimes, and the use or recruitment of child soldiers under sections 1091, 2340, 2340A, 2441, and 2442 of title 18, United States Code, *see* 28 U.S.C. § 509B(e); and (B) conduct that would have been a violation of any such law if the offense had occurred within the jurisdiction of the United States or if the defendant or the victim had been a national of the United States.

'The offense of incitement to genocide' means (A) violations of 18 U.S.C. § 1091(c); and (B) conduct that would have been a violation of such section if the offense had occurred within the jurisdiction of the United States or if the defendant or the victim had been a national of the United States.''.

Chapter Three, Part A is amended by adding at the end the following new guideline and accompanying commentary:

''§ 3A1.5. Serious Human Rights Offense

If the defendant was convicted of a serious human rights offense, increase the offense level as follows:

(a) If the defendant was convicted of an offense under 18 U.S.C. § 1091(c), increase by 2 levels.

(b) If the defendant was convicted of any other serious human rights offense, increase by 4 levels. If (1) death resulted, and (2) the resulting offense level is less than level 37, increase to level 37.

Commentary

Application Notes:

1. *Definition.*—For purposes of this guideline, 'serious human rights offense' means violations of federal criminal laws relating to genocide, torture, war crimes, and the use or recruitment of child soldiers under sections 1091, 2340, 2340A, 2441, and 2442 of title 18, United States Code. *See* 28 U.S.C. § 509B(e).

2. *Application of Minimum Offense Level in Subsection (b).*—The minimum offense level in subsection (b) is cumulative with any other provision in the guidelines. For example, if death resulted and this factor was specifically incorporated into the Chapter Two offense guideline, the minimum offense level in subsection (b) may also apply.

Background: This guideline covers a range of conduct considered to be serious human rights offenses, including genocide, war crimes, torture, and the recruitment or use of child soldiers. *See* generally 28 U.S.C. § 509B(e).

Serious human rights offenses generally have a statutory maximum term of imprisonment of 20 years, but if death resulted, a higher statutory maximum term of imprisonment of any term of years or life applies. *See* 18 U.S.C. §§ 1091(b), 2340A(a), 2442(b). For the offense of war crimes, a statutory maximum term of imprisonment of any term of years or life always applies. *See* 18 U.S.C. § 2441(a). For the offense of incitement to genocide, the statutory maximum term of imprisonment is five years. *See* 18 U.S.C. § 1091(c).''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. § 2425 the following:

''18 U.S.C. § 2441 2X5.1''.

Reason for Amendment: This amendment results from the Commission's multi-year review to ensure that the guidelines provide appropriate guidelines penalties for cases involving human rights violations. This amendment addresses human rights violators in two areas: defendants who are convicted of a human rights offense, and defendants who are convicted of immigration or naturalization fraud to conceal the defendant's involvement, or possible involvement, in a human rights offense.

Serious Human Rights Offenses

First, the amendment addresses defendants whose instant offense of conviction is a ''serious human rights offense.'' In the Human Rights Enforcement Act of 2009, Public Law 111–122 (Dec. 22, 2009), Congress defined ''serious human rights offenses'' as ''violations of Federal criminal laws relating to genocide, torture, war crimes, and the use or recruitment of child soldiers under sections 1091, 2340, 2340A, 2441, and 2442 of title 18, United States Code.'' In that legislation, Congress authorized a new section within the Department of Justice ''with responsibility for the enforcement of laws against suspected participants in [such] offenses.'' That section was established the following year, when the Human Rights and Special Prosecutions Section was created in the Justice Department's Criminal Division. Serious human rights offenses generally have a statutory maximum term of imprisonment of 20 years, but if death resulted, a higher statutory maximum term of imprisonment of any term of years or life applies. *See* 18 U.S.C. §§ 1091(b), 2340A(a), 2442(b). For the offense of war crimes, a statutory maximum term of imprisonment of any term of years or life always applies. *See* 18 U.S.C. § 2441(a). For the offense of incitement to genocide, the statutory maximum term of imprisonment is five years. *See* 18 U.S.C. § 1091(c).

Serious human rights offenses can be committed in a variety of ways, including, for example, assault, kidnapping, and murder. As a result, the guidelines generally have addressed these offenses by referencing them to a number of different Chapter Two offense guidelines, such as §§ 2A1.1 (First Degree Murder), 2A1.2 (Second Degree Murder), 2A2.1 (Assault with Intent to Commit Murder; Attempted Murder), 2A2.2 (Aggravated Assault) and 2A4.1 (Kidnapping, Abduction, Unlawful Restraint). In addition, certain of these Chapter Two offense guidelines use as a base offense level the offense level from another guideline applicable to the underlying conduct (*e.g.,* § 2H1.1 (Offenses Involving Individual Rights), which is the guideline to which genocide offenses are referenced). The offense of committing a war crime in violation of 18 U.S.C. § 2441, however, has not been referenced to any guideline prior to this amendment. The amendment amends Appendix A (Statutory Index) to reference these offenses to § 2X5.1 (Other Felony Offenses). Section 2X5.1 addresses the variety of ways in which a war crimes offense may be committed by generally directing the court to apply the most analogous offense guideline.

The amendment also establishes a new Chapter Three adjustment at § 3A1.5 (Serious Human Rights Offense) if the defendant was convicted of a serious human rights offense. The new guideline provides two tiers of adjustments, corresponding to the differing statutory penalties that apply to such offenses. The adjustment generally provides a 4-level increase if the defendant was convicted of a serious human rights offense, and a minimum offense level of 37 if death resulted. If the defendant was convicted of an offense under 18 U.S.C. § 1091(c) for inciting genocide, however, the adjustment provides a 2-level increase in light of the lesser statutory maximum penalty such offenses carry compared to the other offenses covered by this adjustment.

The new Chapter Three adjustment accounts for the particularly egregious nature of serious human rights offenses while generally maintaining the proportionality

provided by the various Chapter Two guidelines that cover such offenses.

Immigration Fraud

Second, the amendment addresses cases in which the offense of conviction is for immigration or naturalization fraud and the defendant committed any part of the instant offense to conceal the defendant's involvement, or possible involvement, in a serious human rights offense. These offenders are sentenced under § 2L2.2 (Fraudulently Acquiring Documents Relating to Naturalization, Citizenship, or Legal Resident Status for Own Use; False Personation or Fraudulent Marriage by Alien to Evade Immigration Law; Fraudulently Acquiring or Improperly Using a United States Passport). The offenders covered by this amendment fall into two categories. In the first category are defendants who concealed their connection to a military, paramilitary, or police organization that was involved in a serious human rights offense. In the second category are defendants who concealed having participated in a serious human rights offense.

The amendment adds a new specific offense characteristic to § 2L2.2 at subsection (b)(4) that contains two subparagraphs. Subparagraph (A) applies if the defendant committed any part of the instant offense to conceal the defendant's membership in, or authority over, a military, paramilitary, or police organization that was involved in a serious human rights offense during the period in which the defendant was such a member or had such authority, and provides a 2-level increase and a minimum offense level of 13. Subparagraph (B) applies if the defendant committed any part of the instant offense to conceal the defendant's participation in a serious human rights offense, and provides a 6-level increase if the offense was incitement to genocide, or a 10-level increase and minimum offense level of 25 if the offense was any other serious human rights offense. The amendment also adds an application note defining the terms ''serious human rights offense'' and ''the offense of incitement to genocide.''

The new enhancement reflects the impact that such immigration fraud offenses can have on the ability of immigration and naturalization authorities to make fully informed decisions regarding the defendant's immigration petition, application or other request and is intended to ensure that the United States is not a safe haven for those who have committed serious human rights offenses.

6. *Amendment:* The Commentary to § 4A1.2 captioned ''Application Notes'' is amended in Note 5 by striking ''counted. Such offenses are not minor traffic infractions within the meaning of § 4A1.2(c).'' and inserting ''always counted, without regard to how the offense is classified. Paragraphs (1) and (2) of § 4A1.2(c) do not apply.''.

Reason for Amendment: This amendment resolves differences among circuits regarding when prior sentences for the misdemeanor offenses of driving while intoxicated and driving under the influence (and any similar offenses by whatever name they are known) are counted toward the defendant's criminal history score.

Convictions for driving while intoxicated and similar offenses encompass a range of offense conduct. For example, convictions for driving while intoxicated and similar offenses can be classified as anything from traffic infractions to misdemeanors and felonies, and they are subject to a broad spectrum of penalties (ranging from a fine to years in custody for habitual offenders). When the prior offense is a felony, the sentence clearly counts toward the defendant's criminal history score because ''[s]entences for all felony offenses are counted.'' *See* subsection (c) of § 4A1.2 (Definitions and Instructions for Computing Criminal History). However, when the prior sentence is for a misdemeanor or petty offense, circuits have taken different approaches, in part because of language added to § 4A1.2(c)(1). *See* USSG App. C, Amendment 352 (effective November 1, 1990) (adding ''careless or reckless driving'' to the offenses listed in § 4A1.2(c)(1)).

When the prior sentence is a misdemeanor or petty offense, § 4A1.2(c) specifies that the offense is counted, but with two exceptions, limited to cases in which the prior offense is on (or similar to an offense that is on) either of two lists. On the first list are offenses from ''careless or reckless driving'' to ''trespassing.'' In such a case, the sentence is counted only if (A) the sentence was a term of probation of more than one year or a term of imprisonment of at least 30 days, or (B) the prior offense was similar to the instant offense. *See* § 4A1.2(c)(1). On the second list are offenses from ''fish and game violations'' to ''vagrancy.'' In such a case, the sentence is never counted. *See* § 4A1.2(c)(2).

Most circuits have held that driving while intoxicated convictions, including misdemeanors and petty offenses, always count toward the criminal history score, without exception, even if the offense met the criteria for either of the two lists. These circuits have relied on Application Note 5 to § 4A1.2, which has provided:

> *Sentences for Driving While Intoxicated or Under the Influence.*—Convictions for driving while intoxicated or under the influence (and similar offenses by whatever name they are known) are counted. Such offenses are not minor traffic infractions within the meaning of § 4A1.2(c).

See United States v. *Pando,* 545 F.3d 682, 683–85 (8th Cir. 2008) (holding that a conviction for driving while ability impaired was properly included in defendant's criminal history, and rejecting defendant's argument that his offense was similar to careless or reckless driving); *United States* v. *Thornton,* 444 F.3d 1163, 1165–67 (9th Cir. 2006) (holding that driving with high blood alcohol level was properly included in defendant's criminal history, and rejecting defendant's argument that his conviction was ''similar'' to minor traffic infraction or public intoxication). *See also United States* v. *LeBlanc,* 45 F.3d 192, 195 (7th Cir. 1995) (''[A]pplication note [5] reflects the Sentencing Commission's conclusion 'that driving while intoxicated offenses are of sufficient gravity to merit inclusion in the defendant's criminal history, however they might be classified under state law.'''); *United States* v. *Deigert,* 916 F.2d 916, 918 (4th Cir. 1990) (holding that defendant's alcohol-related traffic offenses are counted under Application Note 5).

The Second Circuit took a different approach in *United States* v. *Potes-Castillo,* 638 F.3d 106 (2d Cir. 2011), holding that Application Note 5 could be read either (1) to ''mean that, like felonies, driving while ability impaired sentences are always counted, without possibility of exception'' or (2) ''as setting forth the direction that driving while ability impaired sentences must not be treated as minor traffic infractions or local ordinance violations and excluded under section 4A1.2(c)(2).'' *Id.* at 110–11. The Second Circuit adopted the second reading and, accordingly, held that a prior sentence for driving while ability impaired ''should be treated like any other misdemeanor or petty offense, except that they cannot be exempted under section 4A1.2(c)(2).'' *Id.* at 113. According to the Second Circuit, such a sentence can qualify for an exception, and therefore not be counted, under the first list (*e.g.,* if it was similar to ''careless or reckless driving'' and the other criteria for a first-list exception were met).

The amendment resolves the issue by amending Application Note 5 to clarify that convictions for driving while intoxicated and similar offenses are always counted, without regard to how the offenses are classified. Further, the amendment states plainly that paragraphs (1) and (2) of § 4A1.2(c) do not apply.

This amendment reflects the Commission's view that convictions for driving while intoxicated and other similar offenses are sufficiently serious to always count toward a defendant's criminal history score. The amendment clarifies the Commission's intent and should result in more consistent

calculation of criminal history scores among the circuits.

7. *Amendment:* Section 5G1.2 is amended in subsection (b) by striking ''Except as otherwise required by law (*see* § 5G1.1(a), (b)), the sentence imposed on each other count shall be the total punishment as determined in accordance with Part D of Chapter Three, and Part C of this Chapter.'' and inserting ''For all counts not covered by subsection (a), the court shall determine the total punishment and shall impose that total punishment on each such count, except to the extent otherwise required by law.''.

The Commentary to § 5G1.2 captioned ''Application Notes'' is amended in Note 1, in the first paragraph, by inserting before the period at the end of the first sentence the following: ''and determining the defendant's guideline range on the Sentencing Table in Chapter Five, Part A (Sentencing Table)''; and after the first paragraph, by inserting the following new paragraph: ''Note that the defendant's guideline range on the Sentencing Table may be affected or restricted by a statutorily authorized maximum sentence or a statutorily required minimum sentence not only in a single-count case, *see* § 5G1.1 (Sentencing on a Single Count of Conviction), but also in a multiple-count case. *See* Note 3, below.''; and by redesignating Note 3 as Note 4 and inserting after Note 2 the following:

''3. *Application of Subsection (b).*—

(A) *In General.*—Subsection (b) provides that, for all counts not covered by subsection (a), the court shall determine the total punishment (*i.e.,* the combined length of the sentences to be imposed) and shall impose that total punishment on each such count, except to the extent otherwise required by law (such as where a statutorily required minimum sentence or a statutorily authorized maximum sentence otherwise requires).

(B) *Effect on Guidelines Range of Mandatory Minimum or Statutory Maximum.*—The defendant's guideline range on the Sentencing Table may be affected or restricted by a statutorily authorized maximum sentence or a statutorily required minimum sentence not only in a single-count case, *see* § 5G1.1, but also in a multiple-count case.

In particular, where a statutorily required minimum sentence on any count is greater than the maximum of the applicable guideline range, the statutorily required minimum sentence on that count shall be the guideline sentence on all counts. *See* § 5G1.1(b). Similarly, where a statutorily required minimum sentence on any count is greater than the minimum of the applicable guideline range, the guideline range for all counts is restricted by that statutorily required minimum sentence. *See* § 5G1.1(c)(2) and accompanying Commentary.

However, where a statutorily authorized maximum sentence on a particular count is less than the minimum of the applicable guideline range, the sentence imposed on that count shall not be greater than the statutorily authorized maximum sentence on that count. *See* § 5G1.1(a).

(C) *Examples.*—The following examples illustrate how subsection (b) applies, and how the restrictions in subparagraph (B) operate, when a statutorily required minimum sentence is involved.

Defendant A and Defendant B are each convicted of the same four counts. Counts 1, 3, and 4 have statutory maximums of 10 years, 20 years, and 2 years, respectively. Count 2 has a statutory maximum of 30 years and a mandatory minimum of 10 years.

For Defendant A, the court determines that the final offense level is 19 and the defendant is in Criminal History Category I, which yields a guideline range on the Sentencing Table of 30 to 37 months. Because of the 10-year mandatory minimum on Count 2, however, Defendant A's guideline sentence is 120 months. *See* subparagraph (B), above. After considering that guideline sentence, the court determines that the appropriate 'total punishment' to be imposed on Defendant A is 120 months. Therefore, subsection (b) requires that the total punishment of 120 months be imposed on each of Counts 1, 2, and 3. The sentence imposed on Count 4 is limited to 24 months, because a statutory maximum of 2 years applies to that particular count.

For Defendant B, in contrast, the court determines that the final offense level is 30 and the defendant is in Criminal History Category II, which yields a guideline range on the Sentencing Table of 108 to 135 months. Because of the 10-year mandatory minimum on Count 2, however, Defendant B's guideline range is restricted to 120 to 135 months. *See* subparagraph (B), above. After considering that restricted guideline range, the court determines that the appropriate 'total punishment' to be imposed on Defendant B is 130 months. Therefore, subsection (b) requires that the total punishment of 130 months be imposed on each of Counts 2 and 3. The sentences imposed on Counts 1 and 4 are limited to 120 months (10 years) and 24 months (2 years), respectively, because of the applicable statutory maximums.

(D) *Special Rule on Resentencing.*—In a case in which (i) the defendant's guideline range on the Sentencing Table was affected or restricted by a statutorily required minimum sentence (as described in subparagraph (B)), (ii) the court is resentencing the defendant, and (iii) the statutorily required minimum sentence no longer applies, the defendant's guideline range for purposes of the remaining counts shall be redetermined without regard to the previous effect or restriction of the statutorily required minimum sentence.''.

Reason for Amendment: This amendment responds to an application issue regarding the applicable guideline range in a case in which the defendant is sentenced on multiple counts of conviction, at least one of which involves a mandatory minimum sentence that is greater than the minimum of the otherwise applicable guideline range. The issue arises under § 5G1.2 (Sentencing on Multiple Counts of Conviction) when at least one count in a multiple-count case involves a mandatory minimum sentence that affects the otherwise applicable guideline range. In such cases, circuits differ over whether the guideline range is affected only for the count involving the mandatory minimum or for all counts in the case.

The Fifth Circuit has held that, in such a case, the effect on the guideline range applies to all counts in the case. *See United States* v. *Salter,* 241 F.3d 392, 395–96 (5th Cir. 2001). In that case, the guideline range on the Sentencing Table was 87 to 108 months, but one of the three counts carried a mandatory minimum sentence of 10 years (120 months), which resulted in a guideline sentence of 120 months. The Fifth Circuit instructed the district court that the appropriate guideline sentence was 120 months on each of the three counts.

The Ninth Circuit took a different approach in *United States* v. *Evans-Martinez,* 611 F.3d 635 (9th Cir. 2010), holding that, in such a case, ''a mandatory minimum sentence becomes the starting point for any count that carries a mandatory minimum sentence higher than what would otherwise be the Guidelines sentencing range,'' but ''[a]ll other counts * * * are sentenced based on the Guidelines sentencing range, regardless [of] the mandatory minimum sentences that apply to other counts.'' *See id.* at 637. The Ninth Circuit stated that it would be more ''logical'' to follow the Fifth Circuit's approach but ''such logic is overcome by the precise language of the Sentencing Guidelines''. *See id.*

The District of Columbia Circuit appears to follow an approach similar to the Ninth Circuit. *See United States* v. *Kennedy,* 133 F.3d 53, 60–61 (DC Cir. 1998) (one of two counts carried a mandatory sentence of life imprisonment; district court treated life imprisonment as the guidelines sentence for both counts; Court of Appeals reversed, holding that the appropriate guidelines range for the other count was 262 to 327 months).

The amendment adopts the approach followed by the Fifth Circuit and makes three changes to § 5G1.2. First, it amends § 5G1.2(b) to clarify that the court is to determine the total punishment and impose that total punishment on each count, except to the extent otherwise required by law.

Second, it amends the Commentary to clarify that the defendant's guideline range in a multiple-count case may be restricted by a mandatory minimum penalty or statutory maximum penalty (*i.e.,* a mandatory minimum may increase the bottom of the otherwise applicable guideline range and a statutory maximum may decrease the top of the otherwise applicable guideline range) in a manner similar to how the guideline range in a single-count case may be restricted by a minimum or maximum penalty under § 5G1.1 (Sentencing on a Single Count of Conviction). Specifically, it clarifies that when any count involves a mandatory minimum that restricts the defendant's guideline range, the guideline range is restricted as to all counts. It also provides examples of how these restrictions operate.

Third, it amends the commentary to clarify that in a case in which (1) a defendant's guideline range was affected or restricted by a mandatory minimum penalty, (2) the court is resentencing the defendant, and (3) the mandatory minimum sentence no longer applies, the court shall redetermine the defendant's guideline range for purposes of the remaining counts without regard to the mandatory minimum penalty.

These changes resolve the application issue by clarifying the manner in which the Commission intended this guideline to operate, and by providing examples similar to those used in training probation officers and judges. When there is only one count, the guidelines provide a single guideline range, and that range may be restricted if a mandatory minimum is involved, as described in § 5G1.1 (Sentencing on a Single Count of Conviction). When there is more than one count, the guidelines also provide a single guideline range, and that range also may be restricted if a mandatory minimum is involved. These changes provide clarity and consistency for cases in which a mandatory minimum is present and are intended to ensure that sentencing courts resolve multiple-count cases in a straightforward, logical manner, with a single guideline range, a single set of findings and reasons, and a single set of departure and variance considerations.

8. *Amendment:* Chapter Five, Part K, Subpart 2 is amended by striking § 5K2.19 and its accompanying commentary as follows:

''§ 5K2.19. Post-Sentencing Rehabilitative Efforts (Policy Statement)

Post-sentencing rehabilitative efforts, even if exceptional, undertaken by a defendant after imposition of a term of imprisonment for the instant offense are not an appropriate basis for a downward departure when resentencing the defendant for that offense. (Such efforts may provide a basis for early termination of supervised release under 18 U.S.C. § 3583(e)(1).)

Commentary

Background: The Commission has determined that post-sentencing rehabilitative measures should not provide a basis for downward departure when resentencing a defendant initially sentenced to a term of imprisonment because such a departure would (1) be inconsistent with the policies established by Congress under 18 U.S.C. § 3624(b) and other statutory provisions for reducing the time to be served by an imprisoned person; and (2) inequitably benefit only those who gain the opportunity to be resentenced *de novo*.''.

Reason for Amendment: The Commission's policy statement at § 5K2.19 (Post-Sentencing Rehabilitative Efforts) (Policy Statement) prohibits the consideration of post-sentencing rehabilitative efforts as a basis for downward departure when resentencing a defendant. Section 5K2.19 was promulgated in 2000 in response to a circuit conflict regarding whether sentencing courts may consider such rehabilitative efforts while in prison or on probation as a basis for downward departure at resentencing following an appeal. *See* USSG App. C, Amendment 602 (effective November 1, 2000). This amendment repeals § 5K2.19. The amendment responds to the Supreme Court's decision in *Pepper* v. *United States,* 131 S. Ct. 1229 (2011), which, in part relying on 18 U.S.C. § 3661, held among other things that ''when a defendant's sentence has been set aside on appeal, a district court at resentencing may consider evidence of the defendant's postsentencing rehabilitation.'' The amendment repeals the policy statement in light of the *Pepper* decision.

9. *Amendment:* Section 2P1.2 is amended in subsection (a)(3) by inserting after ''currency,'' the following: ''a mobile phone or similar device,''.

The Commentary to § 2P1.2 captioned ''Application Notes'' is amended by redesignating Notes 1 and 2 as Notes 2 and 3, respectively, and by inserting at the beginning the following:

''1. In this guideline, the term 'mobile phone or similar device' means a phone or other device as described in 18 U.S.C. § 1791(d)(1)(F).''.

The Commentary to § 2T2.1 captioned ''Statutory Provisions'' is amended by inserting ''15 U.S.C. § 377,'' before ''26 U.S.C.''.

The Commentary to § 2T2.2 captioned ''Statutory Provisions'' is amended by inserting ''15 U.S.C. § 377,'' before ''26 U.S.C.''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 15 U.S.C. § 158 the following:

''15 U.S.C. § 377 2T2.1, 2T2.2'';

by inserting after the line referenced to 18 U.S.C. § 43 the following:

''18 U.S.C. § 48 2G3.1'';

by inserting after the line referenced to 18 U.S.C. § 1153 the following:

''18 U.S.C. § 1158 2B1.1, 2B5.3

18 U.S.C. § 1159 2B1.1'';

by inserting after the line referenced to 18 U.S.C. § 1716D the following:

''18 U.S.C. § 1716E 2T2.2''; and

by striking the lines referenced to 41 U.S.C. § 53, 54, and 423(e) as follows:

''41 U.S.C. § 53 2B4.1

41 U.S.C. § 542B4.1

41 U.S.C. § 423(e) 2B1.1, 2C1.1''; and by inserting the following:

''41 U.S.C. § 2102 2B1.1, 2C1.1

41 U.S.C. § 2105 2B1.1, 2C1.1

41 U.S.C. § 8702 2B4.1

41 U.S.C. § 8707 2B4.1''.

Reason for Amendment: This amendment responds to miscellaneous issues arising from recently enacted legislation.

Cell Phone Contraband Act of 2010

First, the amendment responds to the Cell Phone Contraband Act of 2010, Public Law 111–225 (enacted August 10, 2010), which amended 18 U.S.C. § 1791 (Providing or possessing contraband in prison) to make it a class A misdemeanor to provide a mobile phone or similar device to an inmate, or for an inmate to possess a mobile phone or similar device. Offenses under section 1791 are referenced in Appendix A (Statutory Index) to § 2P1.2 (Providing or Possessing Contraband in Prison). The penalty structure of section 1791 is based on the type of contraband involved, and the other class A misdemeanors in section 1791 receive a base offense level of 6 in § 2P1.2. Under the amendment, the class A misdemeanor in section 1791 that applies when the contraband is a cell phone will also receive a base offense level of 6 in § 2P1.2. This change maintains the relationship between the

penalty structures of the statute and the guideline.

Prevent All Cigarette Trafficking Act of 2009

Second, the amendment responds to the Prevent All Cigarette Trafficking Act of 2009 (PACT Act), Public Law 111–154 (enacted March 31, 2010). The PACT Act made a series of revisions to the Jenkins Act, 15 U.S.C. § 375 *et seq.,* which is one of several laws governing the sale, shipment and taxation of cigarettes and smokeless tobacco.

The PACT Act raised the criminal penalty at 15 U.S.C. § 377 for a knowing violation of the Jenkins Act from a misdemeanor to a felony with a statutory maximum term of imprisonment of 3 years. The amendment amends Appendix A (Statutory Index) to reference section 377 offenses to § 2T2.1 (Non-Payment of Taxes) and § 2T2.2 (Regulatory Offenses). These two guidelines are the most analogous guidelines for a section 377 offense because the offense may involve either non-payment of taxes or regulatory offenses. Accordingly, the amendment also amends the Commentary to §§ 2T2.1 and 2T2.2 to add section 377 to their lists of statutory provisions. These lists indicate that § 2T2.1 applies if the conduct constitutes non-payment, evasion, or attempted evasion of taxes, and § 2T2.2 applies if the conduct is tantamount to a recordkeeping violation rather than an effort to evade payment of taxes.

The PACT Act also created a new class A misdemeanor at 18 U.S.C. § 1716E, prohibiting the knowing shipment of cigarettes and smokeless tobacco through the United States mail. The amendment amends Appendix A (Statutory Index) to reference section 1716E offenses to § 2T2.2. Section 2T2.2 is the most analogous guideline because offenses under section 1716E are regulatory offenses.

Animal Crush Video Prohibition Act of 2010

Third, the amendment responds to the Animal Crush Video Prohibition Act of 2010, Public Law 111–294 (enacted December 9, 2010), which substantially revised the criminal offense at 18 U.S.C. § 48 (Animal crush videos). Section 48 makes it a crime to create or distribute an ''animal crush video,'' which is defined by the statute in a manner that requires, among other things, that the depiction be obscene. The maximum term of imprisonment for a section 48 offense is 7 years. The amendment amends Appendix A (Statutory Index) to reference section 48 offenses to § 2G3.1 (Importing, Mailing, or Transporting Obscene Matter; Transferring Obscene Matter to a Minor; Misleading Domain Names). Section 2G3.1 is the most analogous guideline because obscenity is an element of section 48 offenses.

Indian Arts and Crafts Amendments Act of 2010

Fourth, the amendment responds to the Indian Arts and Crafts Amendments Act of 2010, Public Law 111–211 (enacted July 29, 2010), which amended the criminal offense at 18 U.S.C. § 1159 (Misrepresentation of Indian produced goods and services) to reduce penalties for first offenders when the value of the goods involved is less than $1,000. The maximum term of imprisonment under section 1159 had been 5 years for a first offender and 15 years for a repeat offender. The Act retained this penalty structure, except that the statutory maximum term of imprisonment for a first offender was reduced to 1 year in a case in which the value of the goods involved is less than $1,000. The amendment amends Appendix A (Statutory Index) to reference section 1159 offenses to § 2B1.1 (Theft, Property Destruction, and Fraud). Section 2B1.1 is the most analogous guideline because an offense under section 1159 has elements of fraud and deceit.

The amendment also addresses an existing offense, 18 U.S.C. § 1158 (Counterfeiting Indian Arts and Crafts Board trade mark), which makes it a crime to counterfeit or unlawfully affix a Government trademark used or devised by the Indian Arts and Crafts Board or to make any false statement for the purpose of obtaining the use of any such mark. The maximum term of imprisonment under section 1158 is 5 years for a first offender and 15 years for a repeat offender. The amendment amends Appendix A (Statutory Index) to reference section 1158 offenses to both §§ 2B1.1 and 2B5.3 (Criminal Infringement of Copyright or Trademark). These two guidelines are the most analogous guidelines because an offense under section 1158 contains alternative sets of elements, one of which involves trademark infringement and one of which involves false statements.

Public Contracting Offenses

Finally, the amendment responds to Public Law 111–350 (enacted January 4, 2011), which enacted certain laws relating to public contracts as a new positive-law title of the Code—title 41, ''Public Contracts''. As part of this codification, two criminal offenses, 41 U.S.C. § 53 and 423(a)B(b), and their respective penalty provisions, 41 U.S.C. 54 and 423(e), were given new title 41 section numbers: Sections 8702 and 8707 for sections 53 and 54, respectively, and sections 2102 and 2105 for sections 423(a)–(b) and 423(e), respectively. The substantive offenses and their related penalties did not change. The amendment makes changes to Appendix A (Statutory Index) to reflect the renumbering and includes a reference for the new section 2102, whose predecessor section 423(a)–(b) was not referenced in Appendix A. The changes are technical.

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